

Kentucky House Bill 1 Impact Evaluation

Prepared for

The Kentucky Cabinet for Health and Family Services

March 2015

HB1 Evaluation Team*

Institute for Pharmaceutical Outcomes and Policy
Department of Pharmacy Practice and Science
College of Pharmacy
University of Kentucky
Lexington, Kentucky

* Patricia R. Freeman, PhD, RPh
Amie Goodin, MPP, PhD Candidate
SuZanne Troske, MS
Jeffery Talbert, PhD

This project was supported by federal Harold Rogers Grant No. 2011-PM-BX-0007 awarded by the Bureau of Justice Assistance. The Bureau of Justice Assistance is a component of the Office of Justice Programs, which also includes the Bureau of Justice Statistics, the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, the Office for Victims of Crime, the Community Capacity Development Office, and the Office of Sex Offender Sentencing, Monitoring, Apprehending, Registering and Tracking. Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the U.S. Department of Justice.



Institute for Pharmaceutical Outcomes & Policy

CONTENTS

I.	Executive Summary.....	3
II.	Introduction.....	8
III.	Scope of Work.....	9
IV.	Project 1: KASPER Utilization and Controlled Substance Prescribing.....	10
	A. Utilization.....	10
	1. Registrants.....	10
	2. Queries.....	13
	B. Aggregate Controlled Substance Prescribing.....	15
	1. By Schedule.....	15
	2. By Drug Class and Select Drugs.....	18
	3. Relationship between KASPER Queries and Controlled Substance Prescribing.....	29
	C. Project 1 Summary.....	31
V.	Project 2: Stakeholder Interviews/Survey of KASPER Registrants.....	32
	A. Stakeholder Interviews.....	32
	B. Survey of KASPER Registrants.....	37
	C. Project 2 Summary.....	43
VI.	Project 3: Patient Behavior, Prescriber Behavior and Outcomes.....	45
	A. Characterizing the KASPER Dataset.....	46
	B. Controlled Substance Prescribing by Prescriber Type.....	50
	C. Controlled Substance Prescribing at the Patient Level.....	54
	1. By Schedule.....	55
	2. By Drug Class and Select Drug.....	57
	D. Prescriber Behavior.....	61
	1. Volume of Prescriptions Issued.....	61
	2. High Dose Oxycodone Prescribing.....	71
	3. Buprenorphine/Naloxone Prescribing.....	73
	4. Potentially Inappropriate Prescribing	75
	E. Patient Behavior.....	77
	F. Outcomes.....	81
	1. Substance Abuse Treatment Admissions.....	81
	2. Morbidity from Drug Overdose.....	84
	3. Mortality from Drug Overdose.....	85
	G. Project 3 Summary.....	86
	H. Conclusion and Recommendations.....	88
VII.	Appendices.....	89

I. Executive Summary

Background

In 2012, the Kentucky General Assembly passed comprehensive legislation aimed at addressing the continuing problem of prescription drug abuse and diversion. House Bill 1 (HB1), effective July 20, 2012 and outlined in Kentucky Revised Statutes (KRS) 218A.172, made sweeping changes relative to the prescribing and monitoring of controlled prescription drugs in an effort to address the prescription drug abuse problem in Kentucky. HB1 regulated pain clinics and placed new expectations on prescribers and dispensers of controlled substances (CS), including mandatory registration with the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system and the requirement to query the KASPER system under particular circumstances. Additionally, HB1 required dispensers of CS to report dispensing records to KASPER within one day of dispensing.

The requirements for mandatory registration and utilization of KASPER were included to assist prescribers in making appropriate treatment decisions, to identify patients potentially in need of substance abuse treatment interventions and to identify possible doctor shoppers. However, as with any policy change, there was concern over unintended consequences that impacted patients and providers due to implementation of the law. To maximize the effectiveness of HB1 and minimize unintended consequences, a comprehensive assessment of HB1's impact on patients, prescribers, and citizens in Kentucky was needed. The goals of the HB1 Impact Evaluation were to: 1) evaluate the impact of HB1 on reducing prescription drug abuse and diversion in Kentucky; 2) identify unintended consequences associated with implementation of HB1; and 3) develop recommendations to improve effectiveness of HB1 and mitigate unintended consequences.

To achieve these goals three distinct projects were conducted with the following aims. Project 1 was conducted to study changes in KASPER utilization and CS prescribing. Project 2 was a qualitative study designed to collect user perceptions of the effectiveness of KASPER and to identify potential unintended consequences of HB1. Project 3 was conducted to study changes in patient and prescriber behavior and outcomes.

Key Findings

General Impact of HB1

As expected, the total number of CS prescriptions dispensed in Kentucky decreased for the first time since the inception of KASPER in the post-HB1 period, with the numbers of prescriptions dispensed for all Schedules of CS (CII – CV) decreasing by 4 to 8% in the post-HB1 period. While both opioid and benzodiazepine prescribing decreased, stimulant prescribing continued to increase at its previous rate. As HB1 was originally

crafted by the legislature to specifically address the abuse and diversion of Schedule II opioid and Schedule III hydrocodone products, this was the desired outcome. The continued increase in stimulant prescribing is evidence that stimulant prescribing was not the focus of the legislation and argues against a blanket chilling effect of HB1 on CS prescribing.

In interviews and surveys of prescribers, pharmacists and law enforcement when asked about their experience with HB1 and its implementation stated that although there was initial confusion and disruptions to workflow in their professions those have largely been resolved and, for the most part, have not negatively impacted health care professional practices. It should be noted however, that a minority of prescribers indicated they no longer prescribe CS, or prescribe fewer CS, as a result of the HB1 mandate and its burden on their practices.

In the quantitative evaluation, it was found that HB1 had a significant impact on KASPER registration and utilization in these professionals' workplace. As a result of the HB1 mandate, prescriber registrants increased by 262% and the mean number of queries made annually by prescribers increased by 650%. Similarly, pharmacist registrants increased by 322% and mean number of pharmacist queries increased by 124%. The preferential impact on prescriber queries compared to pharmacists was expected, as HB1 did not mandate pharmacists to query KASPER prior to dispensing.

Concurrently, in the interviews and stakeholder surveys, prescribers and pharmacists indicated utilizing more KASPER reports in their practice and discussing KASPER reports with patients and other health care providers more frequently. This observation may be a direct result of the statutory changes in HB1 that authorized providers to provide copies of reports to patients and allowed them to be shared with other health care providers and placed in medical charts. Additionally, the majority of prescriber and pharmacist respondents reported little change in prescribing and dispensing habits since implementation of HB1, although they perceived their prescribing and dispensing behaviors to be monitored more closely.

Impact on Prescriber Behavior

In the post-HB1 period, the number of unique prescribers and unique patients in the KASPER dataset decreased by 14% and 7%, respectively. At any given time throughout the study period, almost two-thirds of the over 55,000 unique prescribers in the KASPER dataset were identified as out-of-state prescribers who, on average, issued only about 10% of all the CS prescriptions reported to KASPER. In contrast, the approximately 14,000 unique Kentucky prescribers identified in the dataset each fiscal year studied, issued over 10 million CS prescriptions or about 90% of the total CS prescriptions reported to KASPER. Interestingly, the number of unique Kentucky prescribers increased each fiscal year studied. Although individual prescribers may have opted out of prescribing CS post-HB1 as suggested from the surveys, overall, the

number of unique Kentucky prescribers issuing CS did not decline. Nurse practitioners (APRNs) as a group represent a small proportion of the overall number of CS prescribers and issue relatively few (<10%) of the CS prescriptions dispensed. However, across the study period, the number of Kentucky APRNs issuing CS prescriptions grew considerably, as did the total and mean number of CS prescriptions dispensed by this group of prescribers. This suggests that this group of CS prescribers may play a role in ensuring access to legitimate CS therapy.

HB1 preferentially impacted patient-level prescribing of specific drug classes and individual drugs within a class. The mean number of prescriptions issued for oxycodone, hydrocodone and oxymorphone - three specific opioids associated with abuse and diversion in Kentucky - decreased in the post-HB1 period, while the mean number of prescriptions per patient for other opioids commonly used to treat chronic cancer pain increased, arguing against an opioid chilling effect of HB1. Similarly, in the drug class benzodiazepines the prescribing of clonazepam, often used for seizure disorders, was less impacted than the prescribing of alprazolam and diazepam, two drugs more commonly associated with abuse. The prescribing of CS in Kentucky remains highly concentrated in the post-HB1 period, with between 80 and 90% of the CS prescriptions dispensed issued by the top decile of prescribers. For opioids specifically, this high concentration may represent referral of patients to pain management specialists. HB1 had a significant impact on potentially inappropriate prescribing behavior as evidenced by decreases in high-dose oxycodone prescribing. Additionally, the number of patients receiving concurrent therapy with a drug combination known as the 'holy trinity' decreased by 30% in the post-HB1 period. Significant increases in prescribing of buprenorphine/naloxone by over 40% in the post-HB1 period is driven by a large increase in the number of buprenorphine/naloxone prescribers, although it is unclear what percentage of this increase is for Medication Assisted Treatment and what is off-label use for treatment of pain.

Overall, these results indicate that HB1 had a significant impact on prescribing behavior, including inappropriate prescribing, either through its strengthened pain clinic regulations that resulted in closure of several pain clinics immediately following HB1 implementation or through changes in prescribing behavior of individual prescribers who make different treatment decisions as a result of querying the KASPER system under the HB1 mandate.

Impact on Patient Behavior (Doctor Shopping)

One of the main patient behaviors legislators hoped to decrease with the passage of HB1 was that of "doctor shopping." For the purposes of this evaluation, doctor shopping was defined as a patient receiving multiple prescriptions from four or more different prescribers and filled at four or more different pharmacies within a three-month period. There is evidence that HB1 significantly impacted doctor shopping behavior as evidenced by an over 50% decrease in the number of patients who met this criterion in

the post-HB1 period. This supports qualitative evidence gleaned from the stakeholder interviews and surveys of KASPER registrants that HB1 significantly impacted doctor shopping and that KASPER is an effective tool to reduce doctor shopping.

In the surveys and stakeholder interviews, prescribers, pharmacists and law enforcement believed KASPER to be more effective at reducing doctor shopping than reducing the abuse and diversion of prescription drugs. This perception may be a direct result of the impact of mandatory registration and greater use of KASPER by these professionals.

Impact on Patient Outcomes

Analysis of the Treatment Episode Dataset (TEDs) revealed that substance abuse treatment admissions for prescription opioids decreased across the study period with a concurrent increase in treatment admissions related to heroin. When expressed as a percent of all treatment admissions, treatment admissions in Kentucky for prescription opioids decreased at a higher rate while treatment admissions related to heroin increased at a higher rate compared to surrounding states. Similarly, hospital discharges and deaths due to prescription opioid overdose in Kentucky declined post-HB1 while hospital discharges and deaths due to heroin overdose increased. These results suggest the morbidity and mortality related to opioid abuse is shifting away from prescription opioids to heroin.

In the surveys and interviews of both prescribers and pharmacists, they indicated that they referred few patients to substance treatment and HB1 has not impacted their rate of referrals. Information gleaned from the stakeholder interviews, coupled with the survey findings suggest substance abuse treatment may be an area where additional policy interventions are warranted.

Unintended Consequences

Several concerns have been raised relative to possible unintended consequences of HB1. For example, it has been suggested that HB1 exerts a chilling effect on CS prescribers such that patients with legitimate medical needs have difficulty accessing CS therapy. Although qualitative evidence from the interviews and surveys suggests that some individual prescribers have opted out of prescribing CS completely as a result of HB1, multiple analyses in this comprehensive evaluation argue against a blanket chilling effect of HB1.

A second unintended consequence often attributed to HB1 is the rise in heroin abuse. It has been hypothesized that diminished access to and increased cost of prescription opioids as a result of HB1 on doctor shoppers for prescription opioids has fueled the increase in heroin abuse. Although simple economic principles argue in favor of this hypothesis, i.e., decreased prescription opioid supply results in increased cost and

lower demand, many factors likely contribute to the rise in heroin abuse indices. In this evaluation, we document changes in heroin abuse indices, including substance abuse treatment admissions, heroin-related hospitalizations and overdose deaths that occur well before implementation of HB1 and appear temporally related to the reformulation of OxyContin® that occurred in late 2010. The observations suggest that although interventions, such as the mandatory use of KASPER included in HB1, did impact prescription opioid supply, alterations in the heroin market were underway prior to HB1 and this policy change should not be characterized as the sole contributor to the rise in heroin abuse in Kentucky.

Summary and Recommendations

This evaluation shows that HB1, which mandated registration and use of KASPER, significantly and preferentially impacted the prescribing of select opioids and benzodiazepines in Kentucky, decreased potentially inappropriate prescribing behavior and decreased patient doctor-shopping behavior. Multiple analyses argue against a blanket chilling effect of HB1, although stakeholders suggest that individual prescribers have opted out of prescribing CS in Kentucky as a result of the HB1 mandate. High-volume prescribers contribute significantly to the overall prescribing of CS in Kentucky and the Cabinet for Health and Family Services should continue to identify and investigate top prescribers for appropriate prescribing practices. Continued analyses of prescribing behavior, patient behavior and outcomes in the post-HB1 period are warranted to determine if the impacts observed in the first year following implementation of HB1 are sustained.

II. Introduction

The abuse and diversion of controlled prescription drugs is a significant and persistent problem in the United States. To begin to address prescription drug abuse in the Commonwealth, on July 15, 1998 the Kentucky Legislature mandated the establishment of an electronic system for monitoring controlled substances (CS) through passage of Kentucky Revised Statute (KRS) 218A.202. The Kentucky All Schedule Prescription Electronic Reporting Program (KASPER) was thus designed. The rules for reporting and access were defined in Kentucky Administrative Regulations (902 KAR 55:110) promulgated on December 16, 1998¹. Data collection from dispensers of CS was initiated on January 1, 1999. The original version of KASPER required dispensers of CS in Kentucky to report dispensing of Schedule II, III, IV and V CS every 16 days.

Significant enhancement of KASPER occurred in 2005 with creation of the enhanced KASPER system (eKASPER). As described in a comprehensive report on Kentucky's prescription monitoring program prepared by the Cabinet for Health and Family Services (CHFS) in 2006, the vision for eKASPER was "to create a system to allow authorized users to request a report through the Internet 24 hours per day, 7 days per week, and to receive the report in real time (within 15 minutes of request) while continuing to allow them to request reports through the mail or by fax."² The eKASPER system was launched on March 16, 2005 and has been recognized at the state and federal levels as a model program. Additionally, as a result of regulatory amendments to 902 KAR 55:110 in 2009, dispensers of CS were required to report dispensing records to KASPER every 7 days.

In 2012, the Kentucky General Assembly passed comprehensive legislation aimed at addressing the continuing problem of prescription drug abuse and diversion. House Bill 1 (HB1), effective July 20, 2012 and outlined in KRS 218A.172³, made sweeping changes relative to the prescribing and monitoring of controlled prescription drugs in an effort to address the prescription drug abuse problem in Kentucky. HB1 regulated pain clinics and placed new expectations on prescribers and dispensers of CS, including mandatory registration with KASPER and the requirement to query the KASPER system under particular circumstances. Additionally, HB1 required dispensers of CS to report

¹ 902 KAR 55:110. Monitoring system for prescription controlled substances; see <http://www.lrc.ky.gov/kar/902/055/110.htm>; last accessed March 6, 2015.

² A Comprehensive Report on Kentucky's Prescription Monitoring Program; see <http://chfs.ky.gov/nr/rdonlyres/7057e43d-e1fd-4552-a902-2793f9b226fc/0/kaspersummaryreportversion2.pdf>; last accessed March 9, 2015.

³ KRS 218A.172. Administrative regulations on prescribing or dispensing of Schedule II controlled substance or Schedule III controlled substance containing hydrocodone; see <http://www.lrc.ky.gov/statutes/statute.aspx?id=41649>; last accessed March 6, 2015.

dispensing records to KASPER within one day of dispensing. The complete text of changes to Kentucky Revised Statutes as a result of HB1 is provided in Appendix I. Appendix II provides a summary of the administrative regulations promulgated by the Kentucky Board of Medical Licensure to meet the statutory requirements of HB1 and its companion 'clean up bill' HB217 passed in the 2013 legislative session.

The requirements for mandatory registration and utilization of KASPER should assist prescribers in making appropriate treatment decisions and identifying patients potentially in need of substance abuse treatment interventions. However, as with any policy change, unintended consequences that impact patients and providers may be associated with HB1 implementation. To maximize the effectiveness of HB1 and minimize unintended consequences, a comprehensive assessment of HB1's impact on patients, prescribers, and citizens in Kentucky was needed.

III. Scope of Work

The HB1 Evaluation Team was engaged by the Kentucky Cabinet for Health and Family Services (CHFS), Office of Inspector General, to conduct a comprehensive evaluation of HB1. The overall goals of the project were to:

1. Evaluate the impact of HB1 on reducing prescription drug abuse and diversion in Kentucky
2. Identify unintended consequences associated with implementation of HB1 that impact patients, providers and citizens of the Commonwealth
3. Develop recommendations to improve effectiveness of HB1 and mitigate identified unintended consequences

To achieve the above goals, three distinct projects were conducted to address the following specific aims:

Project 1: Changes in KASPER Utilization and CS Prescribing

- 1) Assess changes in KASPER utilization since implementation of HB1, including number of registrants, requests and geographic distribution of registrants
- 2) Assess changes in CS prescribing since implementation of HB1, including number of CS prescribed, drugs prescribed and geographic distribution of dispensed prescriptions

Project 2: Stakeholder Interviews and Survey of KASPER Registrants

- 1) Assess KASPER user perceptions of the effectiveness of KASPER and unintended consequences, including any chilling effect of HB1, utilizing surveys and stakeholder interviews

Project 3: Changes in Patient and Prescriber Behavior and Outcomes

- 1) Assess changes in patient and prescriber behavior/characteristics, including doctor shopping and shifts in prescriber type and number and type of CS prescribed
- 2) Assess changes in morbidity/mortality indices since implementation of HB1, including Emergency Department visits and hospital discharges for CS overdose, admission to substance abuse treatment facilities and deaths due to CS overdose.

IV. Project 1: KASPER Utilization and CS Prescribing

Project 1 uses de-identified aggregate administrative data received from CHFS to assess KASPER usage by prescribers, pharmacists and law enforcement and CS dispensing as reported to KASPER from July 2009 to June 30, 2013. This time period was chosen to provide significant baseline data prior to the implementation of HB1 in July 2012 and allow for one-year post implementation analysis for changes in the registration of KASPER users, usage of the database to request reports (queries) and prescribing and dispensing of CS.

A. KASPER Utilization

1. Registrants

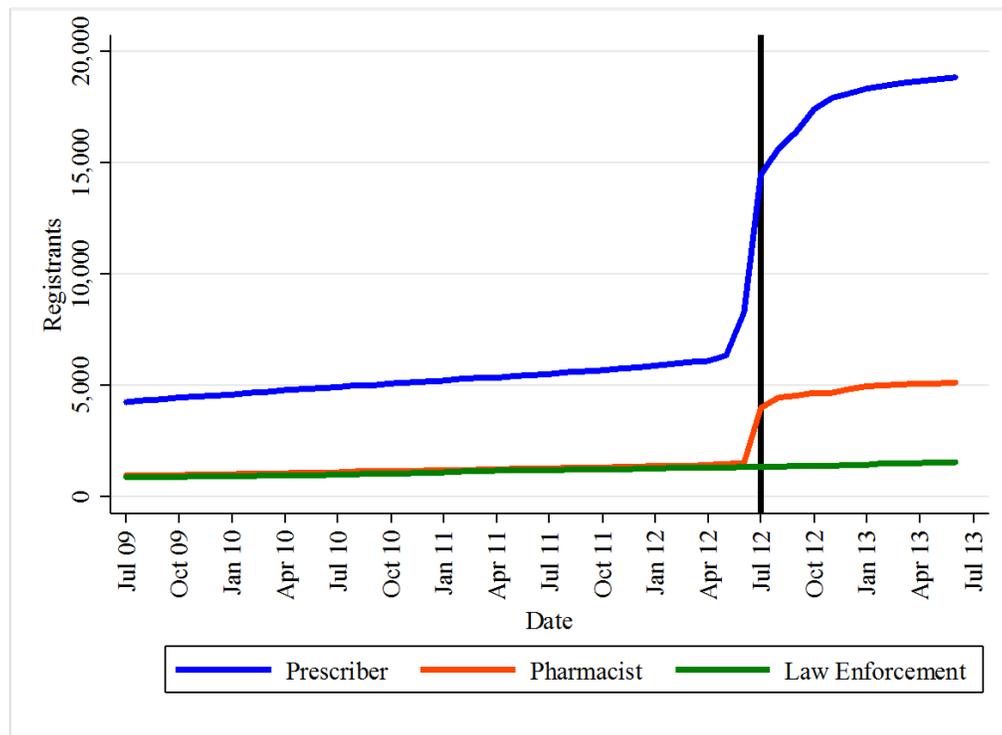
Prior to implementation of HB1, health care professionals prescribing and dispensing CS were under no obligation to utilize the KASPER system. Those with accounts prior to July 2012 voluntarily registered and queried KASPER to assist in treatment decisions. An independent evaluation of the KASPER program in 2010⁴ found that only 27.5% of DEA-licensed prescribers and 16% of licensed pharmacists were registered with KASPER. As a result of HB1, all DEA-licensed prescribers (including physicians, dentists, podiatrists, advanced practice registered nurses, and optometrists) and

⁴ Independent Evaluation of the Impact and Effectiveness of the Kentucky All Schedule Prescription Electronic Reporting Program (KASPER). Available at <http://www.chfs.ky.gov/NR/rdonlyres/24493B2E-B1A1-4399-89AD-1625953BAD43/0/KASPEREvaluationFinalReport10152010.pdf>; last accessed 3-14-15.

pharmacists who worked in DEA-licensed facilities were required to register with KASPER. To assess changes in the number of registrants following implementation of HB1, data were requested from the CHFS on the number of 1) prescribers 2) pharmacists and 3) law enforcement personnel registered with KASPER for the time period July 2009 to July 2013.

Figure 1 shows the total number of KASPER registrants from July 2009 to July 2013. The number of prescriber and pharmacist registrants slowly increased from July 2009 to June 2012. Following implementation of HB1 in July 2012, a sharp increase in the number of prescriber and pharmacist registrants, as expected, is observed. The number of law enforcement registrants steadily increased over this period without the large spike observed for other categories of registrants in July 2012, as the HB1 mandate was specific to prescribers and pharmacists. Between June 2012 (immediately prior to HB1 implementation) and July 2013, prescriber registrants increased by 262% (from 5380 registrants to 14,089 registrants) and pharmacist registrants increased by 322% (from 1,317 registrants to 4,247 registrants).

Figure 1: Total number of Kentucky Prescribers, Pharmacists, and Law Enforcement Registered with KASPER, July 2009 to July 2013



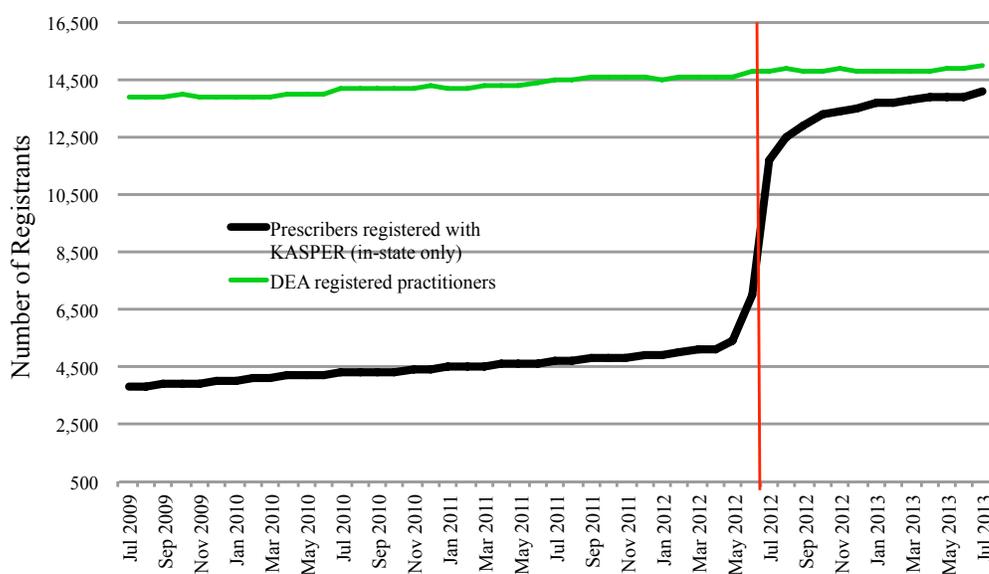
Source: Cabinet for Health and Family Services, KASPER administrative dataset

To determine the percentage of prescribers in the field that were registered with KASPER, data from the Department of Justice, Drug Enforcement Administration

(DEA)⁵ was used to identify the total number of practitioners in Kentucky authorized to prescribe CS by virtue of registering with the DEA and obtaining a DEA number. Figure 2 depicts the number of DEA registered practitioners and the number of prescribers registered with KASPER in Kentucky from July 2009 – July 2013.

As of July 2013, 14,089 prescribers were registered with KASPER while a total of 14,899 Kentucky providers were registered with the DEA. Taken together these data indicate that in July 2013, 95% of practitioners with the authority to prescribe CS via DEA registration were registered with KASPER.

Figure 2: DEA Registered Practitioners and Prescribers Registered with KASPER in Kentucky, July 2009- July 2013



Source: Cabinet for Health and Family Services, KASPER administrative dataset⁷; DEA Registrant dataset

As of July 2013, 4,175 pharmacists were registered with KASPER. Data available from the Kentucky Board of Pharmacy (KYBOP)⁶ showed that 5,062 pharmacists were licensed to practice in the state at that time, indicating that 82.5% of licensed pharmacists were registered with KASPER. It is important to note that an accurate assessment of the number of pharmacists required to register with KASPER by virtue of working in a DEA-licensed facility cannot be made as pharmacists are not required to provide this information to KYBOP nor are they required to register as individuals with the DEA.

⁵ National Technical Information Service, U.S. Department of Commerce, “Active Controlled Substances Act (CSA) Registrants Database: Drug Enforcement Administration, Quarterly DEA File.” 2014. <http://www.ntis.gov/products/dea/>

⁶ Private email communication with Darlene Sayre, Executive Staff Advisor, Kentucky Board of Pharmacy, February 19, 2014.

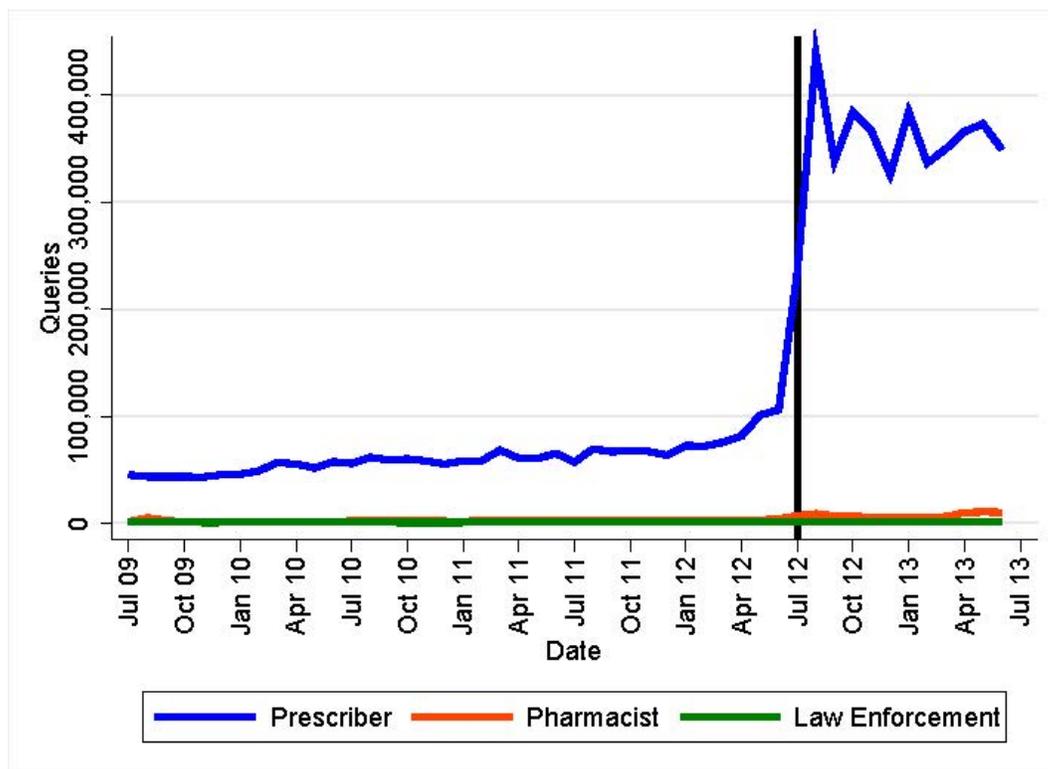
2. Queries

In addition to mandatory registration, HB1 required practitioners with the authority to prescribe CS to query the KASPER system prior to the initial prescribing of Schedule II CS or Schedule III CS containing hydrocodone (See KRS 218A.172 in Appendix I). Additional requirements for querying the KASPER database were outlined in the administrative regulations promulgated by the professional licensing boards (Appendix II).

Prior to July 2012, practitioners prescribing CS were under no obligation to query the KASPER database. It is important to note that although HB1 required pharmacists to register with KASPER, the decision to query the system remains voluntary for this group of healthcare professionals. To assess the changes in registrant queries to KASPER as a result of HB1, data were requested from the CHFS on the number of queries made by registrant type for the time period July 2009 to July 2013.

Figure 3 shows the total number of KASPER queries by registrant type from July 2009 to July 2013. Following implementation of HB1 in July 2012, a sharp increase in the number of prescriber queries is evident. Additionally, an increase in queries by pharmacists is observed post HB1. The number of law enforcement queries did not change significantly over this time period.

Figure 3: Total number of Kentucky Prescribers, Pharmacists, and Law Enforcement Queries to KASPER, July 2009 to July 2013

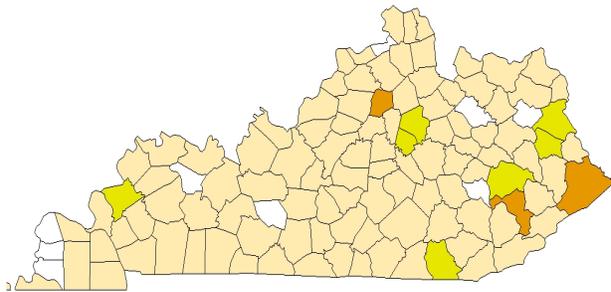


Source: Cabinet for Health and Family Services, KASPER administrative dataset

The mean number of queries made annually by prescribers registered to use KASPER increased from 34 in 2009 to 221 in 2013. In contrast, the mean number of queries made annually by pharmacists registered to use KASPER increased from 21 in 2009 to 26 in 2013.

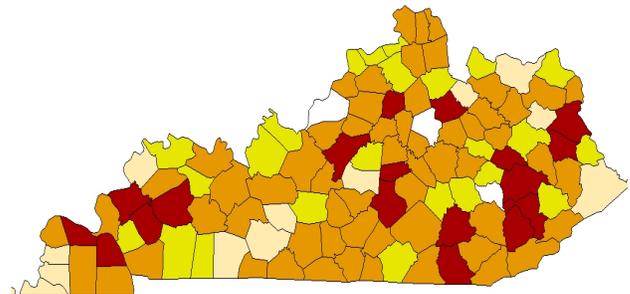
The geographic pattern of queries to KASPER, normalized by county population, for fiscal year (FY) 2010 and in FY 2013 following implementation of HB1 was analyzed for each registrant type. Figures 4a and 4b depict prescriber queries to KASPER by county code of registrant. Significant increases in queries throughout the state are observed following implementation of HB1.

Figure 4a: Prescriber Queries to KASPER by County, Fiscal Year 2010



Source: Cabinet for Health and Family Services, KASPER administrative dataset

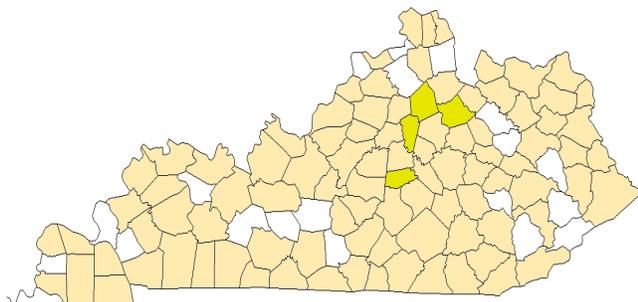
Figure 4b: Prescriber Queries to KASPER by County, Fiscal Year 2013



Source: Cabinet for Health and Family Services, KASPER administrative dataset

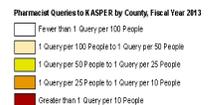
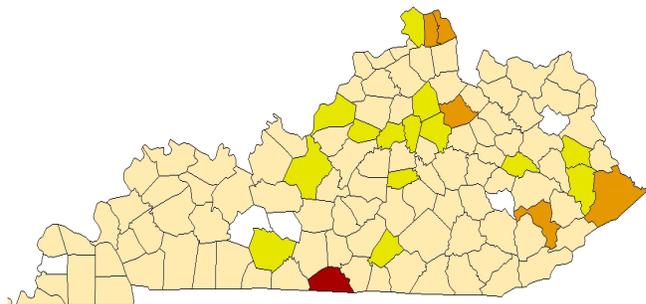
Figures 5a and 5b show the geographic pattern of distribution of pharmacist queries in FY 2010 and FY 2013, respectively. Increases in pharmacist queries are noted sporadically across the state.

Figure 5a: Pharmacist Queries to KASPER by County, Fiscal Year 2010



Source: Cabinet for Health and Family Services, KASPER administrative dataset

Figure 5b: Pharmacist Queries to KASPER by County, Fiscal Year 2013



Source: Cabinet for Health and Family Services, KASPER administrative dataset

Taken together, these data indicate that HB1 significantly impacted the number of queries made by pharmacists and prescribers, with the vast majority from prescribers, as expected. Even though HB1 did not mandate KASPER use by pharmacists, pharmacists are requesting more reports, on average, than they did prior to HB1.

B. Aggregate CS Prescribing

To assess the impact of HB1 on CS prescribing, administrative data from KASPER was used to identify trends in the total number of CS prescriptions dispensed and the number of CS prescriptions dispensed by 1) Schedule; 2) select drug class; and 3) individual select drugs. Drug classes selected were opioids, benzodiazepines and stimulants. Individual drugs within these classes were selected based on ones reported in quarterly KASPER trend reports⁷, ones known to be sought after by doctor-shoppers and ones commonly used for chronic cancer pain. These three analyses were conducted to determine if HB1 preferentially impacted prescribing and dispensing of one Schedule or one drug class over others, and to determine if HB1 selectively impacted the prescribing and dispensing of specific drugs within each class.

1. Prescribing by Schedule

Table 1 shows the number of prescriptions dispensed by Schedule for all prescriptions in the KASPER database for FY 2010 to FY 2013. In FY 2013 following implementation of HB1, the total number of CS prescriptions dispensed decreased for the first time since the inception of the KASPER database, with a 6.4% decrease noted. The number of prescriptions dispensed decreased post-HB1 (FY 2013) for all Schedules (Schedule II – V), ranging from a 4.23% decrease in Schedule II to a 7.06% decrease in Schedule IV. The category ‘Schedule not matched’ represents the number of prescriptions in the KASPER database for which the National Drug Code (NDC) numbers were unable to be matched using the proprietary NDC file provided by Medispan⁸. The significant decreases observed in this category over time may be an indicator of the improvements in data quality submitted by pharmacies to the KASPER system.

⁷ Kentucky Cabinet for Health and Family Services, Office of the Inspector General, “Kentucky All Schedule Prescription Electronic Reporting: Quarterly Trend Report.” 3rd Quarter 2009 to 4th Quarter 2012. Available at <http://www.chfs.ky.gov/os/oig/kaspertrendreports>; last accessed 3-16-15.

⁸ Wolters Kluwer Health, Clinical Solutions. “Medi-Span.” 2014. Available at <http://www.medispan.com/about-us/>; last accessed 3-17-15.

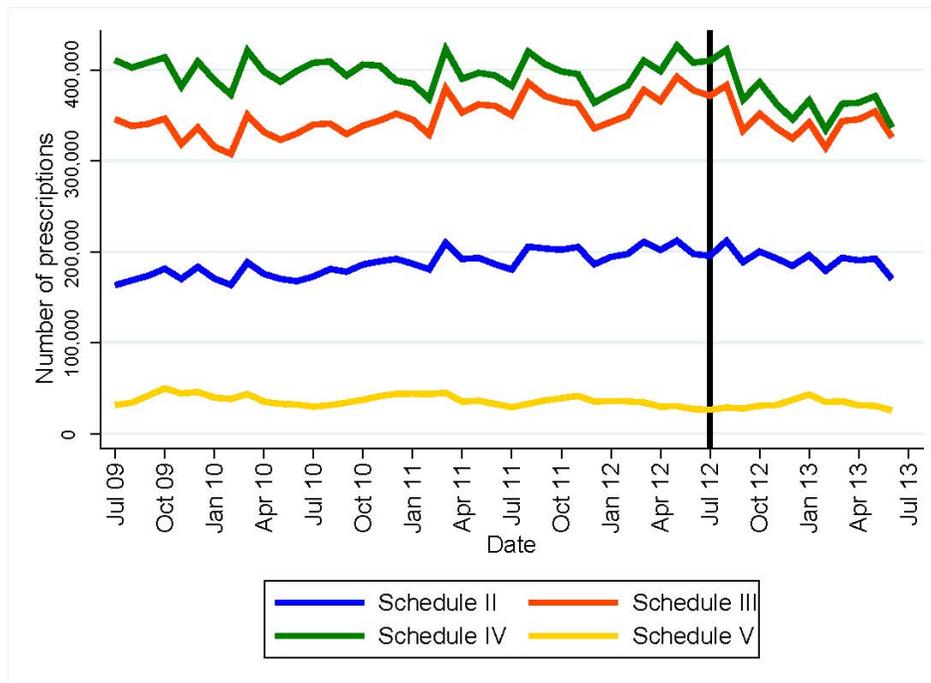
Table 1: Number of Prescriptions Dispensed by Schedule: KASPER, FY 2010 to FY 2013

Schedule dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Schedule II	2,075,764	8.30%	2,248,147	6.63%	2,397,165	-4.23%	2,295,782
Schedule III	3,983,789	4.78%	4,174,081	4.86%	4,376,929	-5.73%	4,126,254
Schedule IV	4,792,657	-0.55%	4,766,508	0.00%	4,766,314	-7.06%	4,430,008
Schedule V	467,894	-3.11%	453,338	-10.44%	406,022	-5.85%	382,258
Schedule not matched	191,091	-21.43%	150,134	-12.86%	130,827	-49.54%	66,020
Total Dispensed	11,511,195	2.44%	11,792,208	2.42%	12,077,257	-6.43%	11,300,322

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Data on the number of CS prescriptions dispensed by Schedule by month from FY 2010 to FY 2013 are plotted in Figure 6. A decrease in number of Schedule III and IV prescriptions are observed immediately following implementation of HB1 in July 2012. Monthly prescriptions dispensed for Schedule II and V are impacted to a lesser degree.

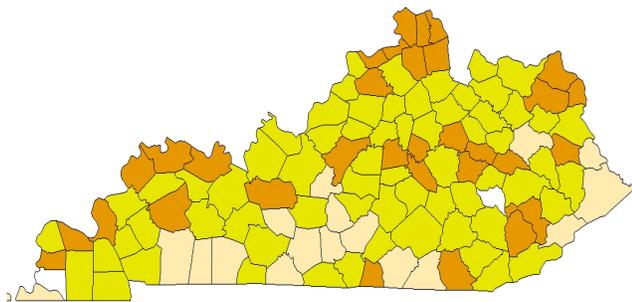
Figure 6: Number of Prescriptions Dispensed by Schedule by Month: KASPER, FY 2010 to FY 2013



Cabinet for Health and Family Services, KASPER administrative dataset

To determine if regional differences in prescribing changed in response to HB1, the number of prescriptions dispensed for Schedule II, III and IV drugs were mapped to the county of patients' residence and normalized based on the population of the county for FY 2010 - FY 2013 (depicted in Figures 7-9). Significant variation exists in the number of Schedule III and IV prescriptions dispensed by county in Kentucky. In FY 2010, the greatest number of Schedule III (Figure 8a) and Schedule IV (Figure 9a) prescriptions per capita were dispensed to patients living in the southeastern and south central areas of Kentucky, with little change in the geographic pattern of dispensing noted following implementation of HB1 (Figures 8b and 9b). The pattern of Schedule II dispensing in FY 2010 and FY 2013 was more consistent across the state (Figures 7a and 7b). Detailed tables and maps summarizing geographic changes in dispensing of Schedule II – V CS medications for the study period can be found in Appendix III and IV.

Figure 7a: Schedule II Prescriptions by County, Fiscal Year 2010

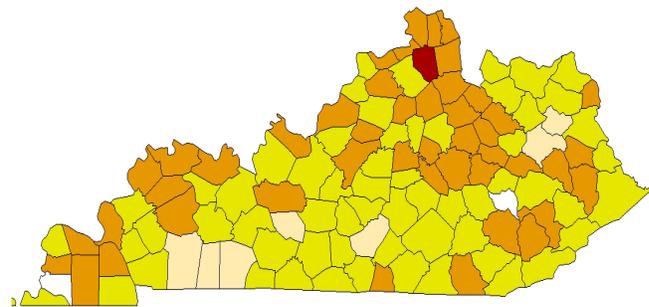


Schedule II Prescriptions by County, Fiscal Year 2010

- Lightest yellow: Fewer than 1 Rx per 5 People
- Light yellow: 1 Rx per 5 People to 1 Rx per 3 People
- Yellow: 1 Rx per 3 People to 1 Rx per 2 People
- Orange: 1 Rx per 2 People to 1 Rx per Person
- Dark orange: Greater than 1 Rx per Person

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Figure 7b: Schedule II Prescriptions by County, Fiscal Year 2013

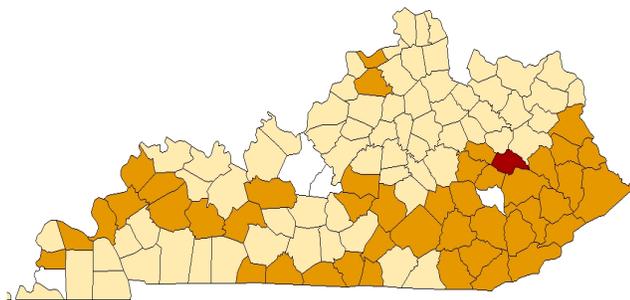


Schedule II Prescriptions by County, Fiscal Year 2013

- Lightest yellow: Fewer than 1 Rx per 5 People
- Light yellow: 1 Rx per 5 People to 1 Rx per 3 People
- Yellow: 1 Rx per 3 People to 1 Rx per 2 People
- Orange: 1 Rx per 2 People to 1 Rx per Person
- Dark orange: Greater than 1 Rx per Person

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Figure 8a: Schedule III Prescriptions by County, Fiscal Year 2010

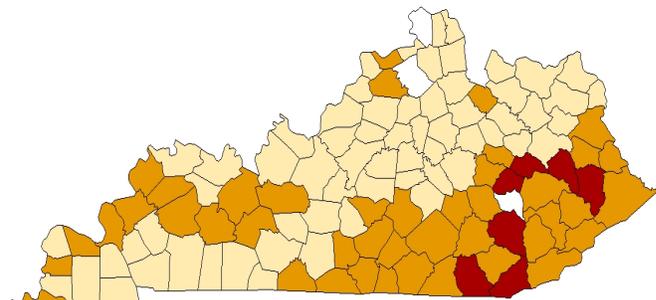


Schedule III Prescriptions by County, Fiscal Year 2010

- Lightest yellow: Fewer than 1 Rx per 2 People
- Light yellow: 1 Rx per 2 People to 1 Rx per Person
- Yellow: 1 Rx per Person to 2 Rx per Person
- Orange: Greater than 2 Rx per Person

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Figure 8b: Schedule III Prescriptions by County, Fiscal Year 2013

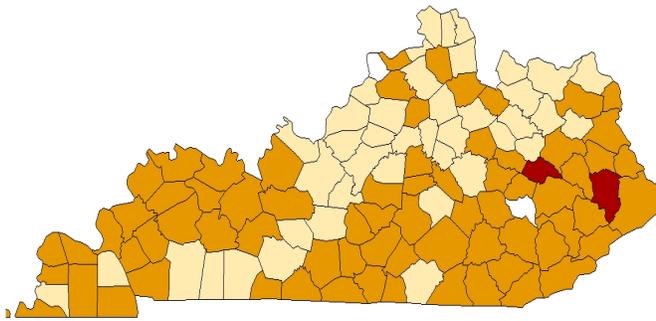


Schedule III Prescriptions by County, Fiscal Year 2013

- Lightest yellow: Fewer than 1 Rx per 2 People
- Light yellow: 1 Rx per 2 People to 1 Rx per Person
- Yellow: 1 Rx per Person to 2 Rx per Person
- Orange: Greater than 2 Rx per Person

Source: Cabinet for Health and Family Services, KASPER administrative dataset

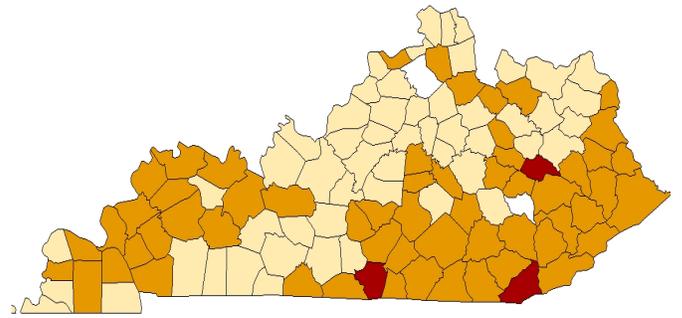
Figure 9a: Schedule IV Prescriptions by County, Fiscal Year 2010



Schedule IV Prescriptions by County, Fiscal Year 2010
 Fewer than 1 Rx per 2 People
 1 Rx per 2 People to 1 Rx per Person
 1 Rx per Person to 2 Rx per Person
 Greater than 2 Rx per Person

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Figure 9b: Schedule IV Prescriptions by County, Fiscal Year 2013



Schedule IV Prescriptions by County, Fiscal Year 2013
 Fewer than 1 Rx per 2 People
 1 Rx per 2 People to 1 Rx per Person
 1 Rx per Person to 2 Rx per Person
 Greater than 2 Rx per Person

Source: Cabinet for Health and Family Services, KASPER administrative dataset

2. Prescribing by Specific Drug Classes and Selected Drugs

To assess the impact of HB1 on CS prescribing by drug class and for select drugs, the total number of prescriptions dispensed were calculated for the opioids (including tramadol), benzodiazepines and stimulant drug classes. Table 2 depicts the percent change in dispensed prescriptions for the drug classes in the three fiscal years prior to HB1 and in FY 2013 following implementation of HB1. Throughout the study period, prescription opioids are the most commonly dispensed class of CS, representing over 50% of all CS prescriptions dispensed and reported to KASPER each year. A significant decrease (8.6%) in the number of opioid prescriptions was observed between FY 2012 and FY 2013 as was a significant decrease (7.65%) in the number of prescriptions written for benzodiazepines. Interestingly, prescriptions dispensed for the stimulant class increased significantly during the entire study period, with an 8.6% increase in number of stimulant prescriptions dispensed between FY 2012 and FY 2013. After removing opioids, benzodiazepines and stimulant drug classes, the remaining classes of CS dispensed showed a 4.98% decrease between FY 2012 and FY 2013 (Table 2, other).

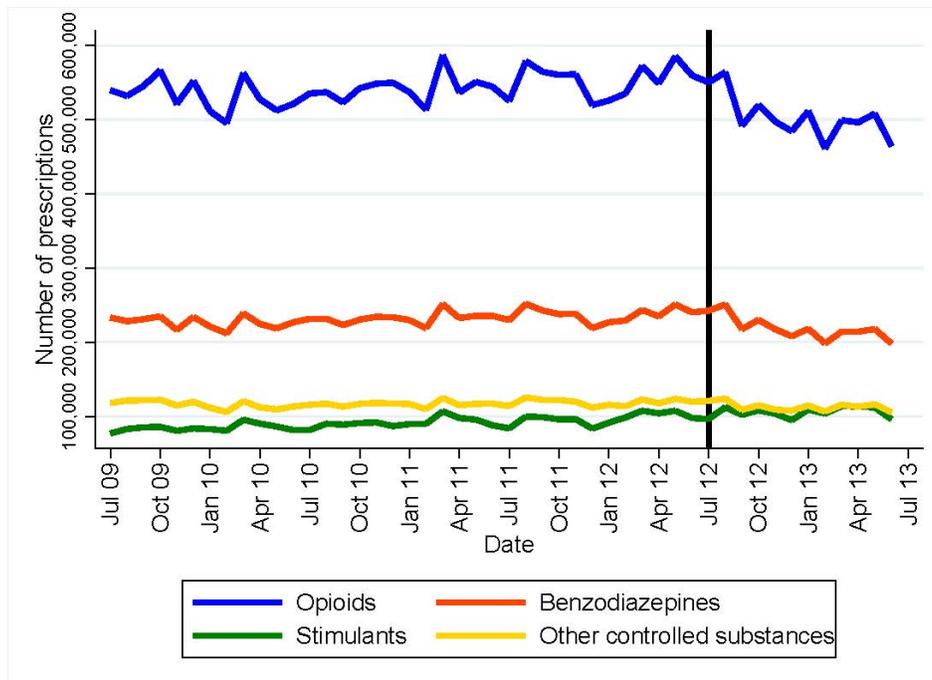
Table 2: Number of Prescriptions Dispensed by Drug Class: KASPER, FY 2010 to FY 2013

Drug class dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Opioids	6,388,835	1.85%	6,506,976	2.02%	6,638,141	-8.86%	6,049,756
Benzodiazepines	2,719,937	2.51%	2,788,275	2.05%	2,845,322	-7.65%	2,627,600
Stimulants	1,012,218	8.47%	1,097,981	6.15%	1,165,476	8.60%	1,265,747
Other	1,390,205	0.63%	1,398,976	2.10%	1,428,318	-4.98%	1,357,219
Total dispensed	11,511,195	2.44%	11,792,208	2.42%	12,077,257	-6.43%	11,300,322

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Data on the number of CS prescriptions dispensed by drug class by month from July 2009 to July 2013 are plotted in Figure 10. A sharp decrease in the number of opioid and, to a lesser extent, benzodiazepine prescriptions is observed immediately following implementation of HB1 in July 2012. Monthly prescriptions dispensed for other CS are impacted to a lesser degree. Monthly prescriptions for stimulants continued to increase throughout the study period.

Figure 10: Number of Prescriptions Dispensed by Drug Class: KASPER, FY 2010 to FY 2013

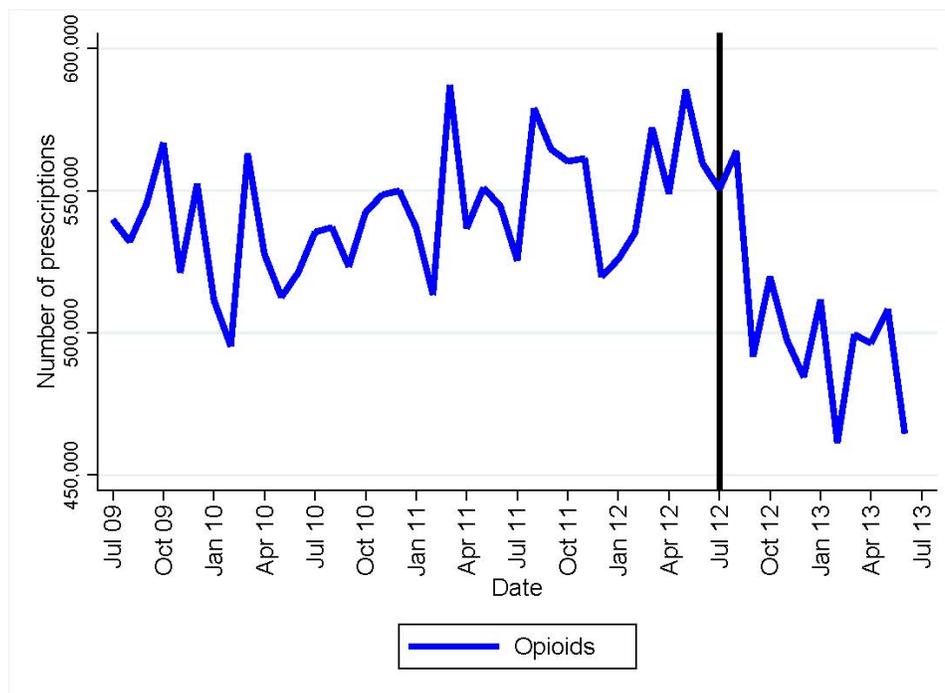


Source: Cabinet for Health and Family Services, KASPER administrative dataset

Opioids

Data on the number of opioid prescriptions dispensed by month from July 2009 – July 2013 are plotted in Figure 11. A sharp decrease in the number of opioid prescriptions is observed immediately following implementation of HB1 in July 2012.

Figure 11: Number of Opioid Prescriptions Dispensed: KASPER, FY 2010 to FY 2013



Source: Cabinet for Health and Family Services, KASPER administrative dataset

Table 3 depicts the number of prescriptions dispensed for select drugs of the opioid class from FY 2010 – FY 2013. Hydrocodone remains the most commonly dispensed opioid in Kentucky with over 3 million prescriptions dispensed each fiscal year studied. Oxycodone is the second most commonly dispensed opioid, with around 1 million prescriptions dispensed each fiscal year. Relatively few prescriptions for hydromorphone and oxymorphone are dispensed in Kentucky. Significant decreases in prescribing of hydrocodone (-13%) oxycodone (-11.8%) oxymorphone (-36.1%) and tramadol (-12.4%) were observed following implementation of HB1 in FY 2013 compared to FY 2012. In contrast, prescriptions dispensed for morphine increased by 2.41% between FY12 and FY13 and prescriptions for hydromorphone and fentanyl decreased by 0.57% and 4%, respectively, during this time frame.

Table 3: Number of Opioid Prescriptions Dispensed by Selected Drugs: KASPER, FY 2010 to FY 2013

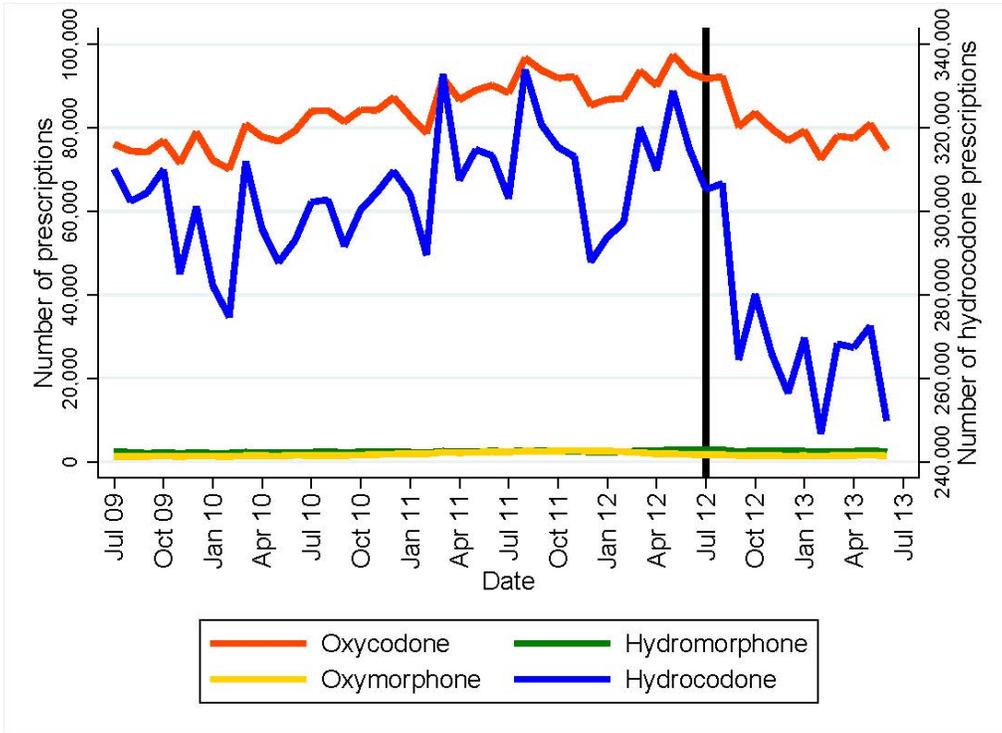
Selected drugs dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Hydrocodone	3,558,356	3.23%	3,673,417	1.78%	3,738,910	-12.99%	3,253,144
Oxycodone	909,322	12.72%	1,025,029	7.00%	1,096,830	-11.76%	967,893
Fentanyl	92,119	-1.06%	91,145	5.48%	96,140	-4.00%	92,299
Morphine	120,518	2.69%	123,761	10.14%	136,316	2.41%	139,601
Hydromorphone	25,685	9.29%	28,072	9.05%	30,613	-0.57%	30,438
Oxymorphone	15,865	39.94%	22,202	24.26%	27,588	-36.09%	17,631
Codeine	353,311	-2.09%	345,938	-12.29%	303,421	-0.85%	300,842
Buprenorphine - total	183,900	24.77%	229,458	47.02%	337,345	43.89%	485,406
Buprenorphine and naloxone combination only	173,878	22.11%	212,323	44.45%	306,702	40.99%	432,409
Methadone	80,019	0.10%	80,099	4.05%	83,344	-7.08%	77,441
Tramadol	570,385	11.50%	635,960	5.57%	671,414	-12.41%	588,105

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Interestingly, prescriptions for buprenorphine increased significantly each fiscal year in the study period, from 183,900 prescriptions in FY2010 to 485,406 prescriptions in FY2013. Additional investigation into the changes in buprenorphine prescribing is described in Project 3.

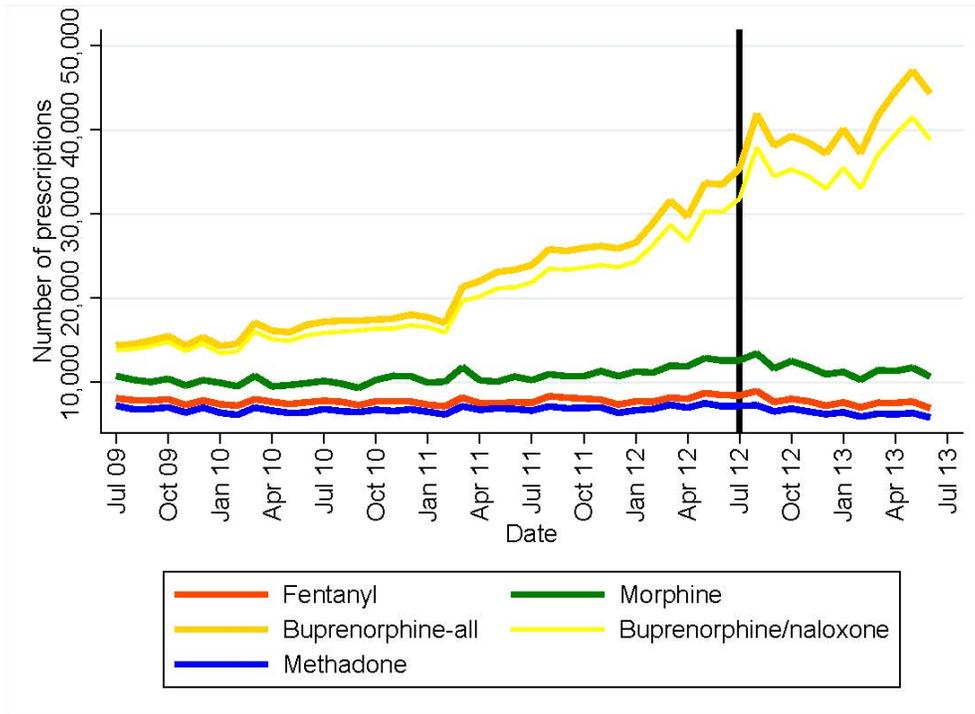
Figures 12a, 12b, and 12c show trends in the number of prescriptions dispensed for these selected opioid drugs by month throughout the study period (July 2009 to July 2013). Immediate decreases in dispensing for hydrocodone and oxycodone (Figure 12a) and tramadol (Figure 12c) are noted following implementation of HB1 in July 2012. Buprenorphine prescriptions continued to increase at a steady rate throughout the study period (Figure 12b).

Figure 12a: Number of Opioid Prescriptions Dispensed by Selected Drugs by Month: KASPER, FY 2010 to FY 2013



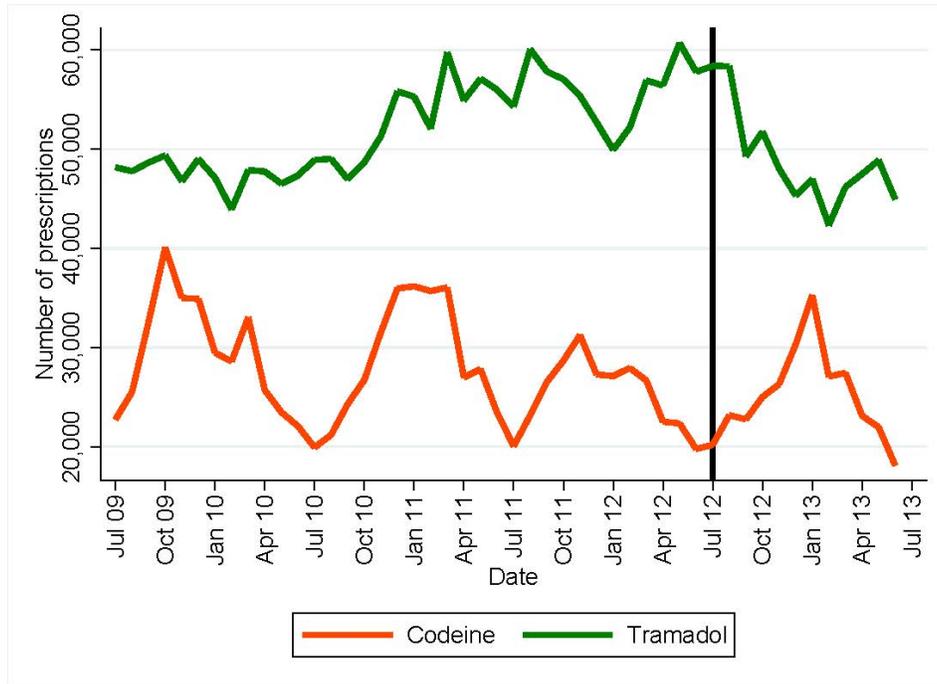
Source: Cabinet for Health and Family Services, KASPER administrative dataset

Figure 12b: Number of Opioid Prescriptions Dispensed by Selected Drugs by Month: KASPER, FY 2010 to FY 2013



Source: Cabinet for Health and Family Services, KASPER administrative dataset

Figure 12c: Number of Opioid Prescriptions Dispensed by Selected Drugs by Month: KASPER, FY 2010 to FY 2013



Source: Cabinet for Health and Family Services, KASPER administrative dataset

To determine how regional differences in opioid dispensing changed in response to HB1, the number of prescriptions dispensed for hydrocodone and oxycodone were mapped to the county of patients' residence and normalized based on the population of the county for FY 2010 and FY 2013. Significant variation exists in the number of hydrocodone prescriptions dispensed by county in Kentucky. In 2010, the greatest number of hydrocodone prescriptions per capita were dispensed to patients living in the southeastern areas of Kentucky (Figure 13a) with little change in the geographic pattern of dispensing noted (Figure 13b) following implementation of HB1. Tables depicting geographic changes in dispensing by drug class and select drug throughout the study period can be found in Appendix III.

Figure 13a: Hydrocodone Prescriptions Dispensed by County, Fiscal Year 2010

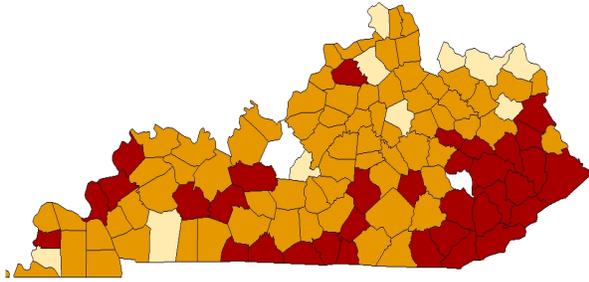


Figure 13b: Hydrocodone Prescriptions Dispensed by County, Fiscal Year 2013

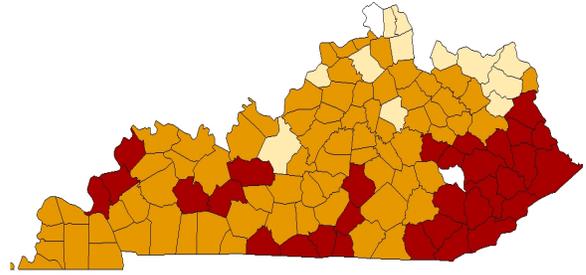


Figure 13c: Oxycodone Prescriptions Dispensed by County, Fiscal Year 2010

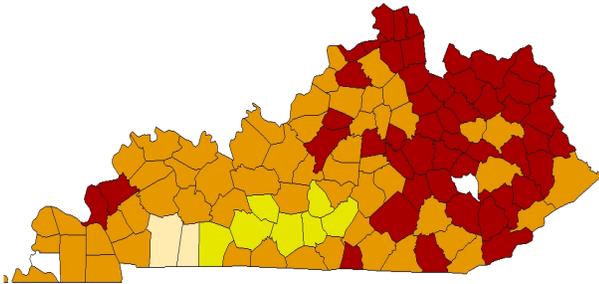


Figure 13d: Oxycodone Prescriptions Dispensed by County, Fiscal Year 2013

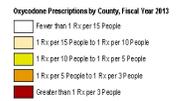
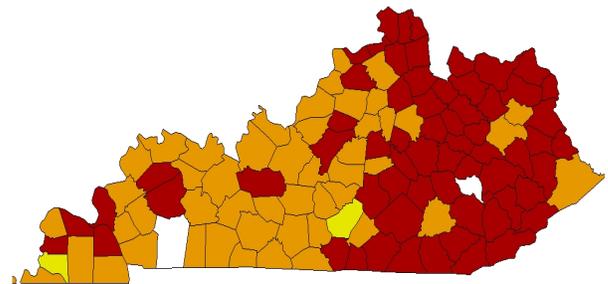


Figure 13e: Buprenorphine Prescriptions Dispensed by County, Fiscal Year 2010

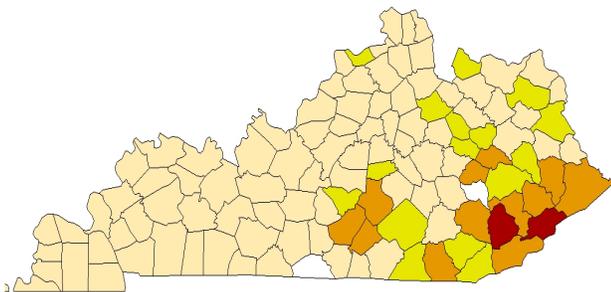
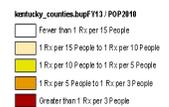
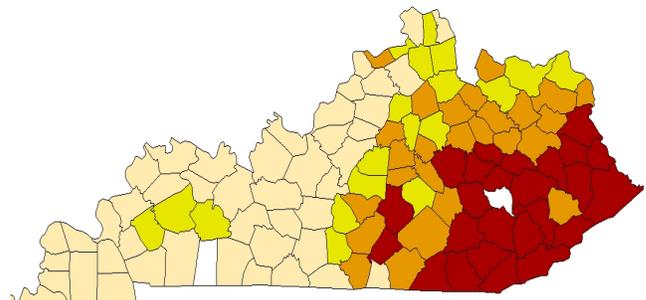


Figure 13f: Buprenorphine Prescriptions Dispensed by County, Fiscal Year 2013



Similarly, significant variation exists in the number of oxycodone prescriptions dispensed by county in Kentucky. In 2010, the greatest numbers of oxycodone prescriptions per capita were dispensed to patients living in the north central and northeast areas of Kentucky (Figure 13c). Except for the increase in oxycodone prescriptions dispensed per capita in southeastern counties, little change in the geographic pattern of dispensing is noted following HB1 implementation (Figure 13d).

Significant variation in buprenorphine prescriptions dispensed by county in Kentucky is observed throughout the study period. As depicted in Figure 13e, the greatest numbers of buprenorphine prescriptions dispensed in FY 2010 were dispensed in the southeastern counties. Significantly more buprenorphine prescriptions per capita were dispensed each year throughout the study period and following HB1 (Figure 13f).

Benzodiazepines

Data on the number of benzodiazepine prescriptions dispensed by month from July 2009 – July 2013 are plotted in Figure 14. A sharp decrease in number of benzodiazepine prescriptions is observed immediately following implementation of HB1 in July 2012.

Figure 14: Number of Benzodiazepine Prescriptions Dispensed by Month: KASPER, July 2009 to July 2013

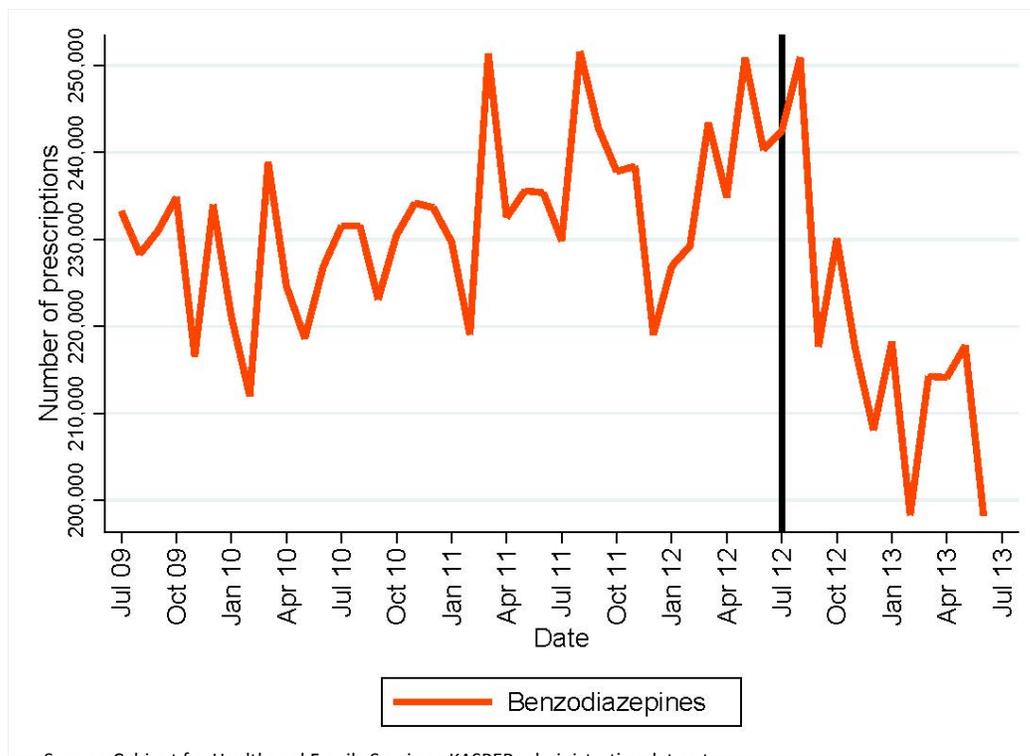


Table 4 shows the number of prescriptions dispensed for selected drugs of the benzodiazepine class from FY 2010 – FY 2013. Significant decreases in prescribing of alprazolam (-10.72%) and diazepam (-9.55%) were observed following implementation of HB1 in FY 2013 compared to FY 2012. Interestingly, prescriptions dispensed for clonazepam decreased by only 2.98% during this time frame. Clonazepam is commonly used for seizure and anxiety disorders and is less often sought after by doctor-shoppers. This preferential impact of HB1 on prescribing of alprazolam and diazepam with less change in prescribing of clonazepam argues against a chilling effect of HB1 on benzodiazepine prescribing.

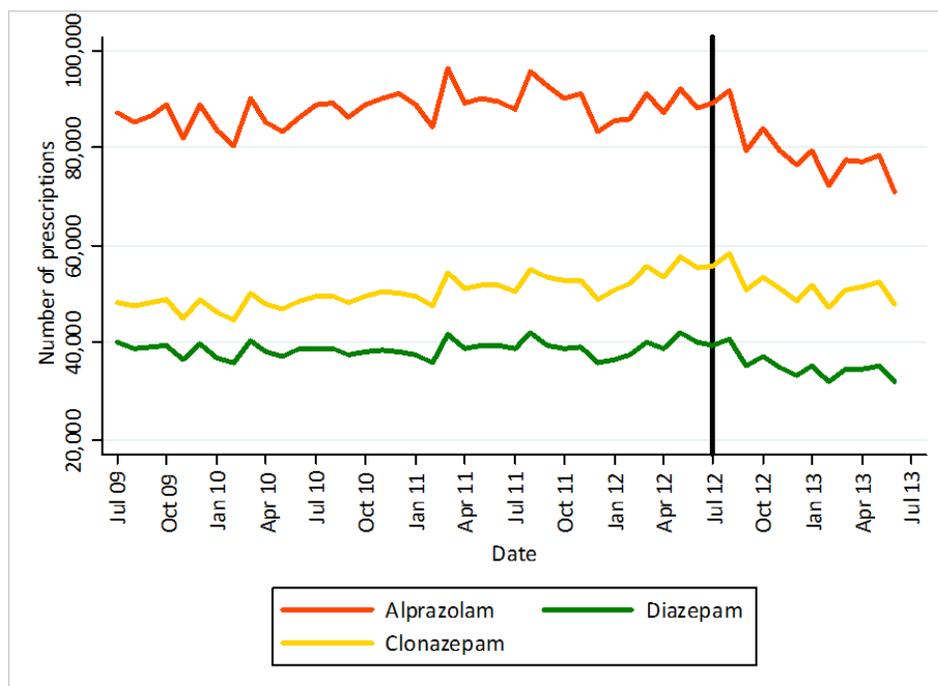
Table 4: Number of Benzodiazepine Prescriptions Dispensed by Selected Drugs: KASPER, FY 2010 to FY 2013

Selected drugs dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Alprazolam	1,029,327	4.39%	1,074,479	-0.23%	1,071,987	-10.72%	957,067
Diazepam	461,329	0.35%	462,949	1.34%	469,143	-9.55%	424,360
Clonazepam	571,601	5.71%	604,214	5.88%	639,712	-2.98%	620,628

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Data on the number of benzodiazepine prescriptions dispensed by month for select benzodiazepines are depicted in Figure 15. Immediate decreases in dispensing of alprazolam, diazepam and to a lesser extent, clonazepam, are noted immediately following implementation of HB1 in July 2012.

Figure 15: Number of Benzodiazepine Prescriptions by Month for Selected Drugs: KASPER, FY 2010 to FY 2013

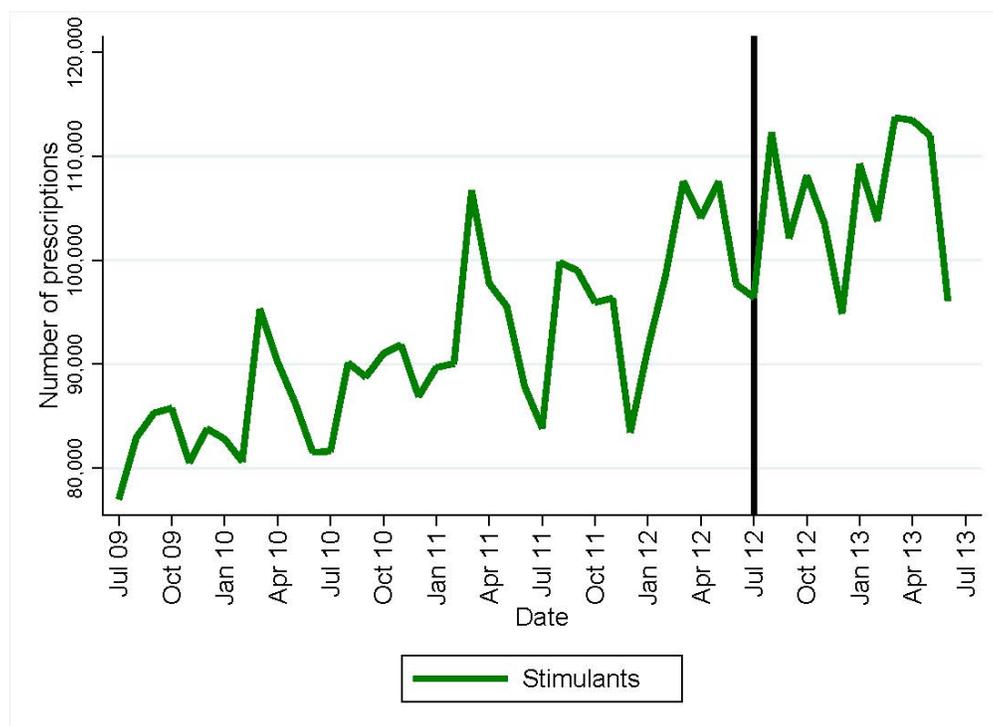


Source: Cabinet for Health and Family Services, KASPER administrative dataset

Stimulants

Data on the number of stimulant prescriptions dispensed by month from July 2009 – July 2013 are plotted in Figure 16. A steady increase in the number of stimulant prescriptions is observed throughout the study period. The fact that stimulant prescriptions continued to increase throughout the study period and in the post HB1 period also argues against a blanket chilling effect of HB1 on prescribers, as if such a chilling effect were occurring one would expect a decrease in prescribing of all CS, regardless of the drug class.

Figure 16: Number of Stimulant Prescriptions Dispensed by Month: KASPER, July 2009 to July 2013



Source: Cabinet for Health and Family Services, KASPER administrative dataset

Table 5 depicts the number of prescriptions dispensed for selected drugs of the stimulant class from FY 2010 – FY 2013. Significant increases in prescribing of all stimulants tested are observed with the exception of dextroamphetamine, which decreased by almost 8% between FY 2011 and FY 2012, and 18.5% between FY 2012 and FY 2013. These data may suggest a shift in stimulant prescribing away from dextroamphetamine to other drugs in the stimulant class perhaps due to shortages of dextroamphetamine reported in 2012⁹.

⁹ ASHP Drug Shortage Bulletin: Dextroamphetamine Tablets; available at <http://www.ashp.org/menu/DrugShortages/ResolvedShortages/Bulletin.aspx?id=853>; last accessed 3-18-15.

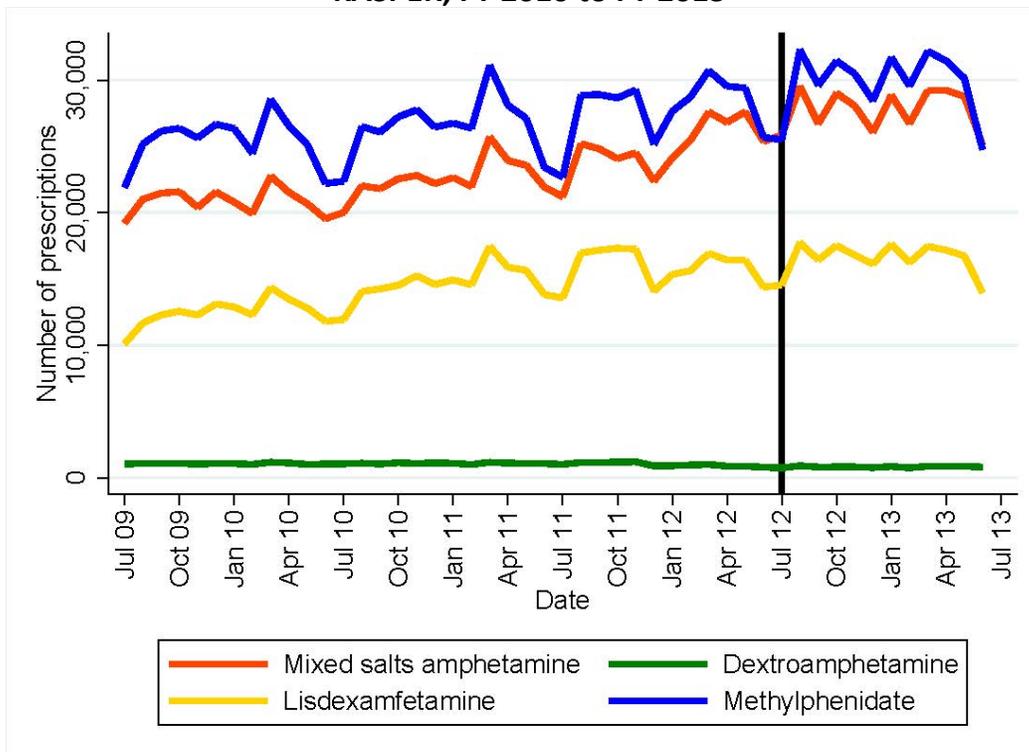
Table 5: Number of Stimulant Prescriptions Dispensed by Selected Drugs: KASPER, FY 2010 to FY 2013

Selected drugs dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Mixed amphetamine salts	250,450	8.25%	271,117	10.32%	299,104	11.37%	333,117
Dextroamphetamine	12,696	1.94%	12,942	-7.97%	11,911	-18.15%	9,749
Lisdexamfetamine	149,529	18.23%	176,789	8.27%	191,404	3.60%	198,300
Methylphenidate	305,147	4.60%	319,169	5.03%	335,218	6.66%	357,534

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Data on the number of stimulant prescriptions dispensed by month for selected stimulants are depicted in Figure 17. Dispensing of select stimulants continues to increase throughout the study period for all stimulants studied with the exception of dextroamphetamine.

Figure 17: Number of Stimulant Prescriptions by Month for Selected Drugs: KASPER, FY 2010 to FY 2013

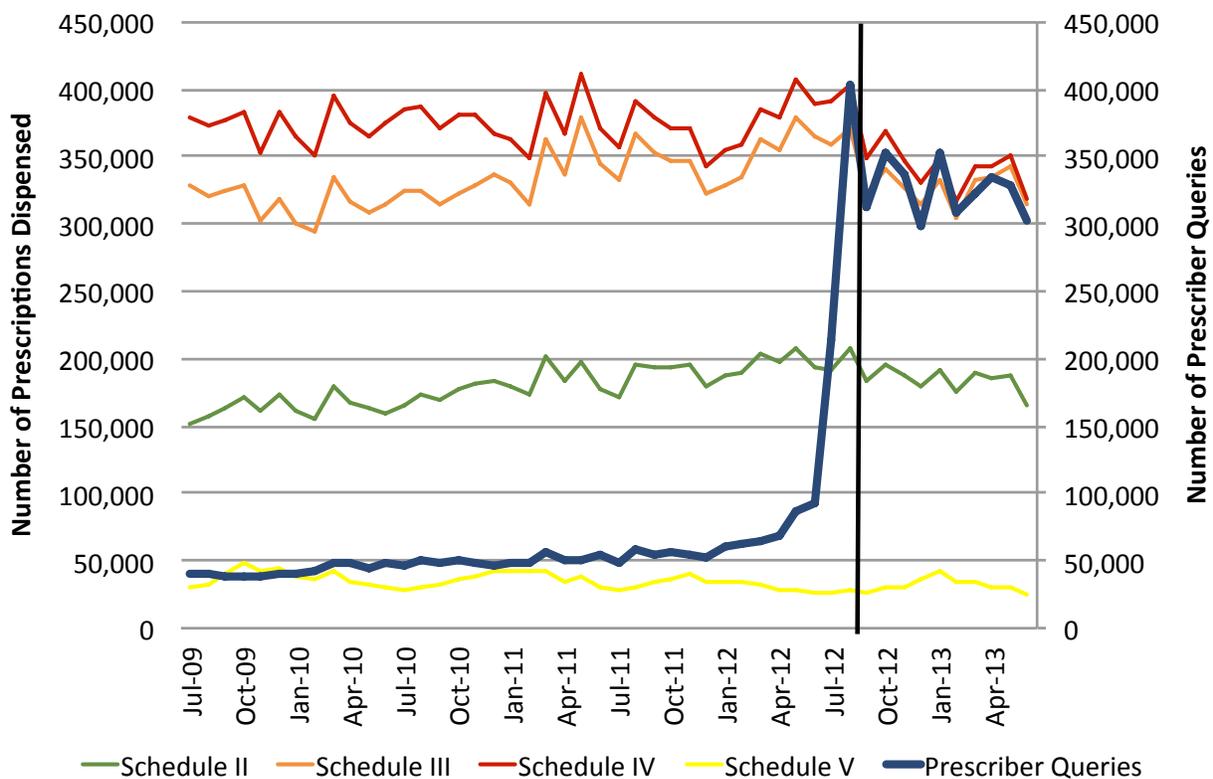


Source: Cabinet for Health and Family Services, KASPER administrative dataset

3. Relationship Between KASPER Queries and CS Prescriptions Dispensed in Kentucky

The overall relationship between KASPER queries and the number of CS prescriptions dispensed by Schedule in Kentucky is depicted in Figure 18. The number of KASPER queries following implementation of HB1 mirrors the pattern of Schedule III and Schedule IV medications dispensed. It is important to note that HB1 mandates that prescribers query KASPER before the initial prescribing of a Schedule II or Schedule III hydrocodone-containing product¹⁰ and then at regular intervals thereafter if the CS medication is continued, and does not require a query prior to prescribing every CS prescription. It will be interesting to note how the relationship between queries and CS prescriptions dispensed changes following rescheduling of the hydrocodone combination products.

Figure 18: Kentucky Prescriber Queries and Prescriptions Dispensed by Schedule, 2009-2013



¹⁰ At the time of this study and passage of HB1, hydrocodone combination products were classified by the DEA as Schedule III medications.

The relationship between KASPER queries and the number of Schedule II, III and IV prescriptions dispensed per capita by county for fiscal years 2010 and 2013 is depicted in Figures 19a and 19b. As previously reported, the total number of KASPER requests increased significantly from FY 2010 to FY 2013, with the heaviest rate of overall usage of KASPER occurring in the eastern and southeastern counties.

Figure 19a: Prescriber Queries to KASPER and Schedules II, III, and IV Prescriptions Dispensed by County, Fiscal Year 2010

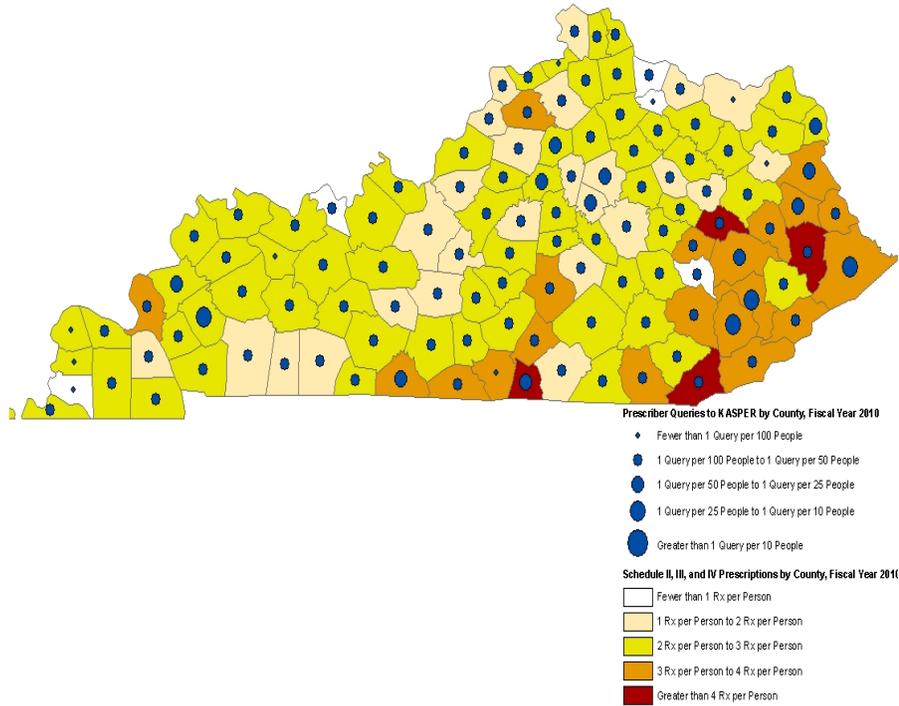
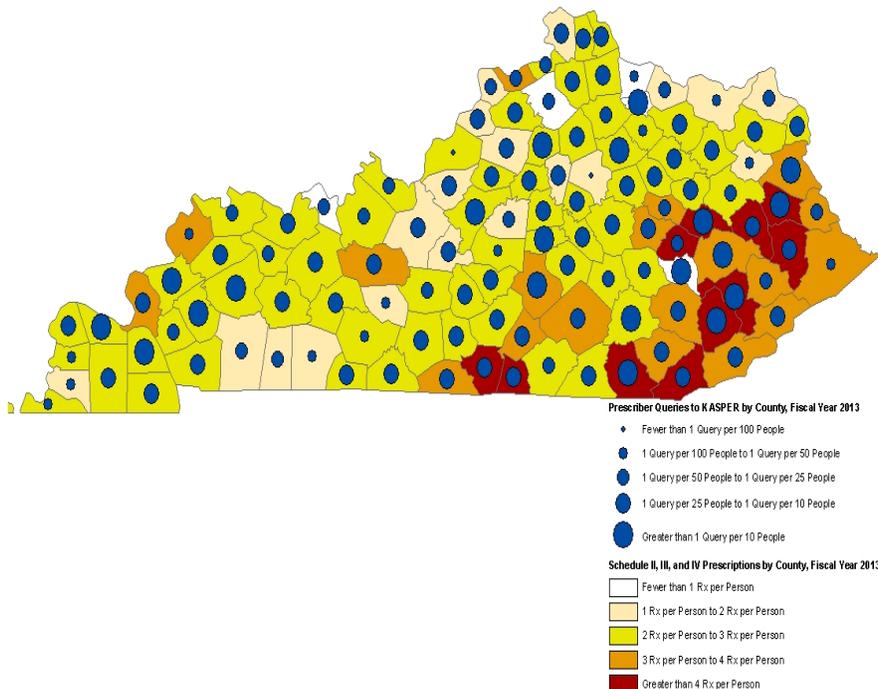


Figure 19b: Prescriber Queries to KASPER and Schedules II, III, and IV Prescriptions Dispensed by County, Fiscal Year 2013



In the post HB1 period (Figure 19b) counties with the greatest number of CS prescriptions dispensed per capita (darker orange) are also counties where the number of KASPER queries is higher per capita (larger blue circle). It is important to note that our analysis is from aggregate data and cannot be used to make explicit conclusions relative to the relationship between CS prescribed in a county and KASPER requests for specific prescriptions, as patients may visit a doctor in one county and live in a different county and vice versa.

C. Project 1 Summary

Overall, the data from Project 1 show that HB1, which mandated CS prescribers and pharmacists working in a DEA-licensed facility register with KASPER, had a significant impact on KASPER registrants, with a 262% increase in prescriber registrants and a 322% increase in pharmacist registrants observed following HB1 implementation. The number of queries made by health care providers to KASPER was also impacted by HB1, with a significant increase in the mean number of queries made annually by prescribers (34 vs. 221) and pharmacists (21 vs. 26). The preferential impact on prescriber queries compared to pharmacists is expected, as HB1 did not mandate pharmacists query of the system prior to dispensing. The fact that the mean number of pharmacist queries increased in the post-HB1 period may be a result of the mandatory registration (if a pharmacist is registered, he/she may be more likely to query the system) or may be the result of policy changes within their practices that require pharmacists to query KASPER under specific circumstances.

The total number of CS prescriptions dispensed in Kentucky decreased for the first time since the inception of KASPER in the post-HB1 period, with the numbers of prescriptions dispensed for all Schedules of CS (CII – CV) decreasing by 4 – 8% in FY 2013. At the drug class level, both opioids and benzodiazepine prescribing decreased as a result of HB1. Interestingly, HB1 had no apparent impact on stimulant prescribing as the prescribing of this drug class continued to increase at about the same rate as it was in the pre-HB1 period. It should be noted that HB1 was originally crafted by the legislature to specifically address rogue pain clinics and the abuse and diversion of Schedule II opioid and Schedule III hydrocodone products. The continued increase in stimulant prescribing as a class, argues against a blanket chilling affect of HB1 on CS prescribing.

HB1 selectively impacted the prescribing of individual drugs within each class. For example, in the opioid class the prescribing of fentanyl and morphine, two drugs commonly used for chronic cancer pain, was impacted much less than the prescribing of hydrocodone, oxycodone, and oxymorphone, drugs historically associated with abuse and diversion in Kentucky. Similarly, prescribing of clonazepam post-HB1 was less impacted than prescribing of alprazolam and diazepam. Buprenorphine prescribing increased by over 40% in the post-HB1 period.

V. Project 2: Stakeholder Interviews and Survey of KASPER Registrants

A. Stakeholder Interviews

Project 2 was a qualitative study designed to gather input from stakeholders relative to the impact of HB1 on drug abuse and diversion, patients, and health care provider practice and to help identify perceptions of stakeholders and KASPER registrants relative to any unintended consequences of HB1.

A. Stakeholder Interviews

The HB1 evaluation team worked with CHFS representatives to identify key stakeholders; broad representation of stakeholders was needed to identify impacts and unintended consequences. Stakeholders were identified for each group of registrants (prescribers, pharmacists and law enforcement) and included their respective licensure boards and professional associations. Eleven focused interviews with stakeholders were conducted between November 1, 2013 and January 17, 2014 (Table 6). In total, 78 individuals participated in these stakeholder interviews. Of the originally planned stakeholder interviews, only the Kentucky Dental Association interview was unable to be scheduled.

Table 6: KASPER Stakeholder Interviews

Profession	Number of participants
Pharmacy	27
Kentucky Board of Pharmacy	8*
Kentucky Pharmacists Association	19
Nursing	14
Kentucky Board of Nursing	5*
Kentucky Coalition of Nurse Practitioners and Nurse Midwives	9
Medicine	22
Kentucky Board of Medical Licensure	6*
Kentucky Medical Association	16
Dentistry	2
Kentucky Board of Dentistry	2*
Law Enforcement	7
Operation Unite	3

NADDI – Kentucky Chapter	3
Kentucky State Police	1
Kentucky Cabinet for Health and Family Services / Medicaid Officials	6

**Includes Legal Counsel for the Board*

Questions for the stakeholder interviews were tailored based on profession and/or type of stakeholder group. The overall objective of the interviews was to gather opinions and impressions from each stakeholder group pertaining to mandated changes in the KASPER program resulting from HB1. The KASPER-related changes were implemented on July 20, 2012. Table 7 contains an overview of the items discussed during the interviews. The University of Kentucky Institutional Review Board (IRB) reviewed the protocol for these interviews and ruled that this aspect of the overall HB1 evaluation was not considered “research involving human subjects” because opinions were sought from Boards or other bodies, not individual human subjects. At the beginning of each interview session, the research team leader and discussion moderator informed participants that during the interview session they were speaking on behalf of their stakeholder organization, not on behalf of themselves, and that because of this, informed consent for participation was not required. Dr. Freeman moderated the discussions while other members of the research team took notes. There were no recordings (audio/video) during the interviews and meeting notes did not attribute comments to specific individuals.

Table 7. HB1 Changes to KASPER Addressed in Stakeholder Interviews

Licensure Board Interview Questions
• Has the Board received feedback from licensees about mandatory registration?
• Has the Board received feedback from licensees about daily reporting?
• Has the Board received feedback relative to the quality of KASPER data?
• How has the Board been impacted by the KASPER-related changes mandated by HB1?
• How does the Board use KASPER as an investigative tool? Has this changed since implementation of HB1?
• Has prescriber / pharmacist use of KASPER changed since HB1 implementation?
• Does the Board have any indication that suggests prescribers / dispensers have altered their controlled substance prescribing / dispensing as a result of the KASPER-related requirements of HB1?
• HB1 allows KASPER reports to be placed in the patient’s medical record and authorized sharing reports between patients and health care providers. What impact does the Board believe this has had on intra- and inter-professional communication? What impact has this had on communication with patients?
• Has the Board received feedback from practitioners relative to HB1-related changes in the KASPER program?
• Has the Board received feedback from consumers relative to HB1-related changes in the KASPER program?
• Do you have additional information about HB1-related changes in the KASPER program you would like to share?

Professional Association Interview Questions
<ul style="list-style-type: none"> • What feedback has the Association received about mandatory registration / mandatory prescriber use / daily reporting from pharmacies?
<ul style="list-style-type: none"> • Has the Association received feedback relative to the quality of data submitted from pharmacies to KASPER?
<ul style="list-style-type: none"> • Has the Association received feedback from members about difficulty correcting inaccurate data in KASPER?
<ul style="list-style-type: none"> • Does the Association have any information related to members' use of KASPER?
<ul style="list-style-type: none"> • Does the Association have any indication that suggests pharmacists / providers have altered their dispensing / prescribing of CS as a result of the KASPER-related requirements of HB1?
<ul style="list-style-type: none"> • HB1 allows KASPER reports to be placed in the patient's medical record, and authorized sharing reports between patients and health care providers. What impact does the Association believe this has had on intra- and inter-professional communication? What impact has this had on communication with patients?
<ul style="list-style-type: none"> • Has the Association received any feedback from members that suggests patients are affected by the KASPER-related requirements of HB1? If so, in what way(s)?
<ul style="list-style-type: none"> • Has the Association received any feedback from members relative to unintended consequences of the KASPER-related requirements of HB1?
<ul style="list-style-type: none"> • Do you have additional information about HB1-related changes in the KASPER program you would like to share?
Law Enforcement Officials Interview Questions
<ul style="list-style-type: none"> • What is the <group's> general impression of the impact of KASPER-related changes to HB1?
<ul style="list-style-type: none"> • How have KASPER-related changes to HB1 impacted drug diversion investigators' ability to investigate cases?
<ul style="list-style-type: none"> • Has the number of investigations changed since KASPER-related changes to HB1? If so, how?
<ul style="list-style-type: none"> • Which KASPER-related HB1 changes have had the greatest impact on drug diversion investigations?
<ul style="list-style-type: none"> • Have you observed changes in investigations/arrests in the type of prescription controlled substance abused since July 2012?
<ul style="list-style-type: none"> • Have you observed changes in investigations/arrests for other abused substances (other than prescription controlled substances) since July 2012?
<ul style="list-style-type: none"> • How have communications/interactions with other law enforcement agencies (KSP, DEA) changed since KASPER-related HB1 changes were implemented?
<ul style="list-style-type: none"> • How have communications/interactions with health care professionals or medical licensing boards changed since KASPER-related HB1 changes were implemented?
<ul style="list-style-type: none"> • Do you have any information that suggests prescribers have altered their controlled substance prescribing as a result of the KASPER-related requirements of HB1?
<ul style="list-style-type: none"> • Do you have any information that suggests pharmacists have altered their dispensing of controlled substances as a result of the KASPER-related requirements of HB1?
<ul style="list-style-type: none"> • Does <group>have any information relative to the unintended consequences of KASPER-related HB1 changes?
<ul style="list-style-type: none"> • Do you have additional information about HB1-related changes in the KASPER program you would like to share?
Kentucky Cabinet for Health and Family Services
<ul style="list-style-type: none"> • How has Medicaid been impacted by KASPER-related HB1 changes (staff, recipients, resources, pharmacists, and providers)?
<ul style="list-style-type: none"> • How has Medicaid's use of KASPER changed since HB1?

<ul style="list-style-type: none"> • How has the Office of Inspector General (OIG) been impacted by KASPER-related HB1 changes (staff and resources)?
<ul style="list-style-type: none"> • Has OIG received any feedback from prescribers, dispensers, consumers or Licensure Boards regarding KASPER-related HB1 changes?
<ul style="list-style-type: none"> • Have operations (e.g., time to deliver a KASPER report or system down time) changed since HB1-related requirements were implemented?
<ul style="list-style-type: none"> • How have the timeliness and/or accuracy of KASPER data changed since HB1 changes were implemented?

Summary of Stakeholder Interviews

Not surprisingly, all health professional stakeholders acknowledged an initial state of confusion and disruption associated with the implementation of KASPER-related HB1 provisions. Many health professionals were unsure of KASPER registration requirements, resulting in numerous phone calls and emails to Licensure Boards and the Office of Inspector General for clarification. Overall, the interviews revealed a generally positive assessment of HB1-related KASPER changes, tinged with some degree of frustration. However, the research team concludes that much of the frustration was due to initial implementation challenges (e.g., the registration process, re-thinking workflow, etc.) and a natural human tendency to mistrust and/or dislike change, particularly mandated change. (To quote one law enforcement participant *“Doctors and other health providers are like police: they don’t like change and they don’t like being told what to do by the legislature.”*) Because the interviews began in November 2013, fifteen months after HB1-related KASPER changes were implemented, most of the initial confusion and turmoil reported by stakeholders had been replaced by acceptance, and, even to some extent, appreciation for enhancements to promoting appropriate CS prescribing and dispensing for citizens within the Commonwealth.

Most stakeholders believe that the profession least impacted by KASPER-related HB1 changes was pharmacy. However, some stakeholders, most notably pharmacist stakeholders, commented that daily reporting was an initial hurdle for some pharmacists, and software limitations required ongoing vigilance to ensure that software “updates” did not revert back to seven-day reporting.

Stakeholders (physicians, nurse practitioners and to a lesser degree, dentists)¹¹ reported that workflow changes stemming from the implementation of KASPER-related HB1 changes in July 2012 initially caused disruption and frustration. The carefully orchestrated and often frenzied workflow that typically characterizes health care facilities (i.e., prescriber offices, clinics and hospitals) clearly was impacted by the requirement for assessing KASPER reports prior to issuing a CS prescription. Several stakeholders reported that the most practical way to address this requirement was to

¹¹ Information from the dental profession was restricted to an interview with the Executive Director of the Board of Dentistry and the Board’s Legal Counsel; therefore, it is not clear that perceptions of actively practicing dentists were fully represented.

run KASPER reports first thing each morning for all patients scheduled for appointments that day. Then, should a KASPER report be needed for a specific patient seen that day, the report would already be available with the patient's chart. Those who reported using this method noted that it was working well for them, although it did necessitate some additional effort from either themselves, or (more often) their delegated support staff. The capability to delegate the task of running the KASPER report was greatly appreciated by the practitioners. While practitioners do not believe that reviewing a KASPER report is particularly onerous, they do note some level of uncertainty regarding how to interpret reports that document potentially questionable CS use in patients who clearly have diagnoses indicative of CS therapy. The sentiment that practitioners, in general, are not extremely confident in their knowledge related to addiction and addiction therapy was heard to varying degrees in all interviews.

Most stakeholders agreed that despite a small number of ongoing issues, KASPER data quality was acceptable. Prescribers were, naturally, very keen on having 100% accurate and up-to-date data while law enforcement personnel were very satisfied with both the timeliness and accuracy of the data. This slight divergence in opinions related to data quality may be a reflection of how the different stakeholders use KASPER data. When prescribers use KASPER data, they are in the midst of issuing a prescription that will imminently be delivered to the patient, and they do not have the resources available to "double-check" the information contained within the KASPER report. In contrast, when law enforcement personnel access KASPER data, they typically are not planning to act on findings for several hours, or perhaps even days, and prior to acting on KASPER information, original copies of prescriptions and/or other records are obtained. Concerns related to 'blended' KASPER reports (i.e., reports that co-mingle data from two separate individuals who live in close proximity and happen to share the same name and birthdate) were reported in nearly all stakeholder interviews.

Mandatory use of KASPER received mixed views. Prescriber groups described both ends of the spectrum on this issue, noting that for some, mandatory use "diluted" the impact of KASPER reports, making them a mind-numbing routine; however, for others, mandatory use removed the "targeting" or "stigma" perception by patients that some had previously associated with KASPER use.

Some provisions in the HB1-related KASPER changes were overwhelmingly endorsed as positive. For example, the provision allowing inclusion of KASPER reports in patient charts was praised by all stakeholder groups with the exception of pharmacy, where the provision appears to have been initially misperceived as a requirement for pharmacies to maintain patient charts, a very uncommon practice within most current pharmacies. Sharing KASPER reports with patients was also seen as a helpful change, facilitating conversations between patients and providers.

All stakeholders perceived a decline in doctor shopping since KASPER-related HB1 changes were implemented, and this sentiment was especially pronounced in the law

enforcement interviews. Most groups noted the temporal association between HB1 implementation and increase in heroin overdoses; however, most participants affirmed that HB1 is just one of several factors (e.g., increased supply and potency of heroin, decreased cost of heroin, and the reformulation of OxyContin®) converging simultaneously with increased heroin overdoses.

Finally, nearly all stakeholders commented that overall, HB1 changes did not include adequate provisions for ensuring treatment for individuals who are dependent on prescription CS. The KASPER-related HB1 changes, as well as the pain-clinic changes, will undoubtedly expose a new population of individuals requiring therapy for detoxification, abstinence promotion and behavioral change. Lack of availability and/or access to substance abuse treatment was noted as a concern by most stakeholders.

B. KASPER Registrant Surveys

Survey Methodology

To evaluate the impact of HB1 and perceived effectiveness of KASPER, all groups of KASPER registrants, including prescribers, pharmacists and law enforcement officials were surveyed via email. The CHFS provided a list of all email addresses of users registered within the KASPER system. All KASPER registrants received an email inviting them to participate in a survey assessing opinions and beliefs about the KASPER program after HB1 implementation. The initial email contained an invitation from the University of Kentucky to complete the survey and a link that re-directed respondents to a web-based application called Research Electronic Data Capture (REDCap), which is designed to exclusively support data capture for research studies. Once the link was clicked, REDCap displayed the survey cover letter that informed the respondent of the study purpose along with provisions for confidentiality of responses.

Survey invitations were emailed to 17,440 prescribers, 5,521 pharmacists, and 1,729 law enforcement officials registered with the KASPER system on January 12, 2015. Those who did not respond to the survey following the initial invitation were emailed a reminder invitation on January 19, 2015, and then a second, final, reminder on January 26, 2015. The surveys were closed and no longer accepted responses on February 2, 2015.

The survey did not collect personally identifying information and REDCap was not used to store unique identification numbers to link back to the email address associated with the response. Survey responses were compiled and frequencies were calculated for each question.

The Institutional Review Boards of both the University of Kentucky and CHFS approved the survey protocol. The survey instruments are included in Appendix V.

Survey Findings

Overall, 1,479 responses were received from the prescriber survey; 534 responses were received from the pharmacist survey; and 232 responses were received from the law enforcement survey. Registrants to whom the survey email could not be distributed due to invalid email addresses, as well as registrants who informed the research team they were no longer in practice or practiced outside of Kentucky were counted and removed from the initial list of emails in order to calculate survey response rates. The response rates for each group were as follows: 9.2% for prescribers, 10.2% for pharmacists, and 17.4% for law enforcement personnel (Table 8). Due to the relatively low response rate, the results should be carefully considered in light of the potential for non-response bias.

Table 8: KASPER Survey Response Rates

Group Surveyed	Total Emails Sent	Invalid Emails	Responses Received	Response Rate
Prescribers	17,440	1307	1,479	9.2%
Pharmacists	5,521	284	534	10.2%
Law Enforcement	1,729	399	232	17.4%

1. Prescribers

The vast majority (79.9%) of respondents were physicians, followed by dentists (19.6%). Less than 1% of respondents identified themselves as nurse practitioners. Family practice (18.5%), internal medicine (9.7%), emergency medicine (10.7%) and other (39.1%) were the most common identified physician specialties.

Use and Interpretation of KASPER Reports

Over half (55.7%) of the prescribers responding indicated they were registered with KASPER prior to the HB1 mandate and reported using a mean of 13.4 KASPER reports in the past week. Prescribers make significant use of delegates with the majority (51.3%) indicating a personal or facility delegate requests the KASPER reports utilized in their practices. When questioned about the accuracy of information in the reports, 76.8% agree or strongly agree that the information presented in KASPER reports is accurate and almost two-thirds (63.5%) are confident in their ability to interpret the information in the KASPER report, although a significant minority (21.6%) strongly disagreed with this statement.

Discussion of KASPER Reports

Almost one-fourth (23.6%) of responding prescribers discuss KASPER reports with their

patients frequently, while one-third (33.9%) indicated they sometimes discuss KASPER reports with patients. Less than 15% indicate they never discuss KASPER reports with patients. When questioned about how the frequency of their discussions has changed since HB1, the majority (57%) indicated no change in their discussions, while 41% reveal they discuss KASPER reports with patients more frequently since implementation of HB1, confirming stakeholder interview findings.

Similarly, 41.9% of prescriber respondents indicated they frequently or sometimes discuss KASPER reports with other health care practitioners with almost three fourths (73.2%) indicating the frequency of their discussions of KASPER reports with other health care practitioners has not changed since implementation of HB1. In contrast, prescriber respondents report they rarely (41.9%) or never (32.2%) discuss KASPER reports with pharmacists and this behavior has not changed since implementation of HB1.

Impact of HB1 on Prescribing Behavior

The vast majority (73.7%) of prescriber respondents believe their CS prescribing behaviors are being more closely monitored since implementation of HB1. The majority (60.8%) of prescribers perceive no change in their CS prescribing patterns as a result of HB1 while one-third (33.4%) report a decrease in CS prescribing. Interestingly, a small minority (3.6%) indicated they no longer prescribe CS as a result of HB1. For those reporting a decrease in their CS prescribing since HB1, the main reason given for this decrease was “Implementation of HB1 requiring mandatory use of KASPER has created a burden on my practice” (22%). Other prominent reasons for those reporting a decrease in CS prescribing were “Implementation of HB1 requiring mandatory use of KASPER has allowed me to more easily identify possible doctor shoppers” (17.2%) and “I refer more patients to pain management specialists since HB1” (15.5%). For those prescribers reporting a change in prescribing since HB1, the perceived impact on their ability to manage their patients is split, with 43% indicating a negative impact on their ability to manage their patients and 38% reporting no impact on their ability to manage their patients.

Impact of HB1 on Doctor-Shopping Behavior

When questioned about suspicions of doctor shopping and/or diverting, most prescribers (54.2%) indicated they had suspected between 1 and 20 patients of these behaviors during the time period since HB1. About one-third (30.4%) reported they had suspected no patients of doctor-shopping behavior while just over 15% (15.4%) reported suspecting more than 20 patients of doctor-shopping behavior. Although the majority (69.2%) perceive their suspicions about doctor-shopping patients have not changed since HB1, a minority (15.1%) reveal they suspect more patients of doctor-shopping since HB1, with an equal number of respondents (15%) reporting they suspect fewer patients of doctor-shopping since HB1.

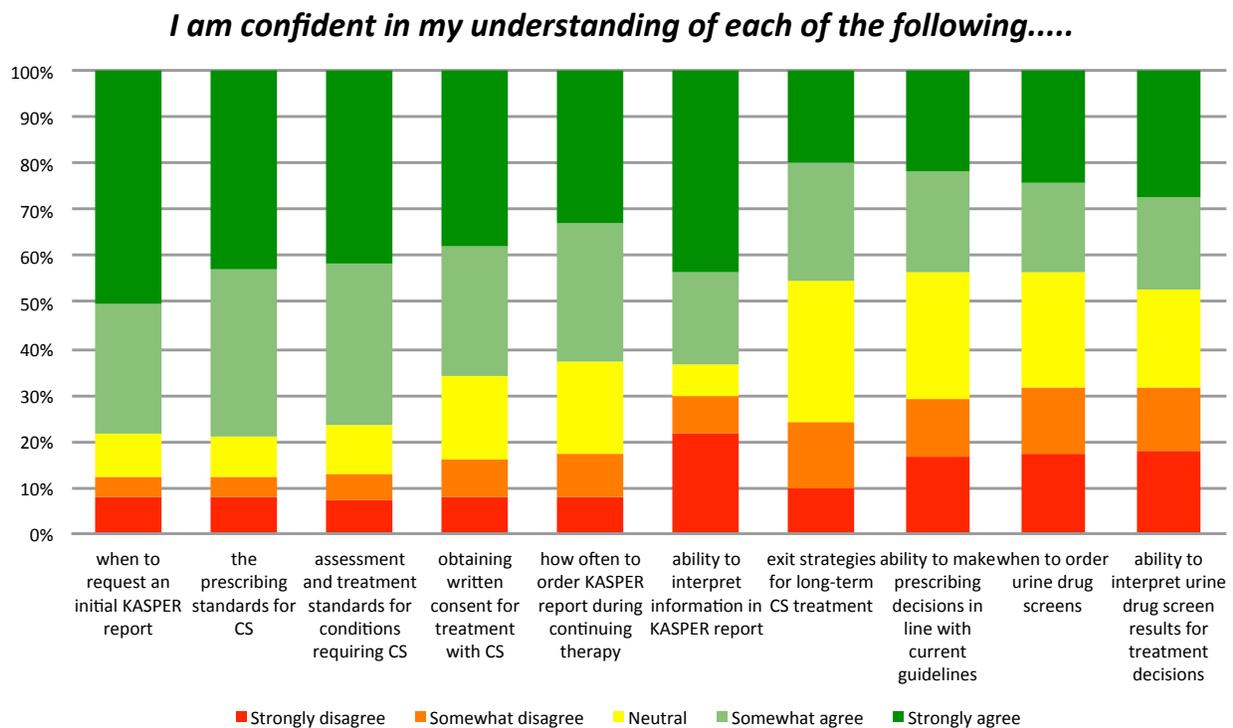
Dismissal/Referral of Patients

Over 70% of prescriber respondents report dismissing no patients from their practice as a result of information in KASPER reports since HB1. Of the remaining respondents, about 20% report dismissing 1 – 5 patients from their practice since HB1, 5% report dismissing 6 – 20 patients from their practice as a result of HB1 and 3.6% report dismissing more than 20 patients from their practice as a result of information in KASPER reports since HB1. Overall, only about one-fourth (28.2%) of prescribers report referring patients to substance abuse treatment with the vast majority (88.4%) reporting no change in referral habits since implementation of HB1.

Prescribing Regulations

When questioned about their confidence in the CS prescribing regulations promulgated by the licensing boards as a result of HB1, interestingly, several areas were identified as possible areas where additional education might be warranted (Figure 20).

Figure 20: KASPER Survey of Prescribers



For example, items where less than 50% of prescriber respondents answered somewhat or strongly agreed included: exit strategies for long-term CS treatment, prescribing decisions in line with current pain treatment guidelines, and when to order and how to interpret urine drug screens.

Effectiveness of KASPER

To assess the perceived effectiveness of KASPER as a tool to reduce doctor shopping, all three user groups were asked to rate the effectiveness of KASPER in this regard using the scale: *not effective at all*, *somewhat ineffective*, *somewhat effective*, *very effective* or *neutral*. Approximately 60% of prescriber respondents believe KASPER is effective¹² at reducing abuse and diversion, while over 70% view KASPER as effective in reducing doctor- shopping.

The full results of the prescriber survey are presented in Appendix VI.

2. Pharmacists

Almost 40% of respondents reported practicing in the chain/supermarket/mass merchandiser pharmacy setting, one-fourth (26.8%) of respondents practiced in the independent pharmacy setting and almost one-fifth (19.6%) of respondents practiced in the hospital setting.

Use and Interpretation of KASPER Reports

Over half (57.8%) of the pharmacists responding indicated they were registered with KASPER prior to the HB1 mandate and reported using a mean of 3.09 KASPER reports in the past week. Pharmacists most often request reports themselves, although a small number (3.4%) indicated pharmacy technicians requested the reports for them. When questioned about the accuracy of information in the reports, 87.6% strongly agree or agree that the information presented in KASPER reports is accurate and almost all (94.3%) are confident in their ability to interpret the information in the KASPER report.

Discussion of KASPER Reports

Pharmacists seldom discuss the contents of KASPER reports with patients, with almost 80% of respondents indicating they rarely (44.3%) or never (35.1%) discuss reports with patients. When questioned about how the frequency of their discussions with patients has changed since HB1, the vast majority (83.1%) indicated no change in their discussions, while 16.4% reveal they discuss KASPER reports with patients more frequently since implementation of HB1.

Similarly, 53.1% of pharmacist respondents indicated they rarely (38.8%) or never (14.3%) discuss KASPER reports with other pharmacists, with over three-fourths (79.3%) indicating the frequency of their discussions of KASPER reports with other pharmacists has not changed since implementation of HB1. In contrast, the majority of pharmacist respondents (59.6%) reveal they frequently (8.1%) or sometimes (51.6%) discuss KASPER reports with prescribers, with over one-third (34.3%) indicating they

¹² "Effective" defined as somewhat effective and very effective combined.

discuss reports with prescribers more frequently since implementation of HB1.

Impact of HB1 on Dispensing Behavior

Although the majority (59.8%) of pharmacist respondents believe their CS dispensing behaviors are being more closely monitored since implementation of HB1, 68.5% perceive no change in their CS dispensing patterns as a result of HB1. Of the remaining respondents, 10.4% report an increase in CS dispensing and 20.8% report a decrease in CS dispensing since HB1. For those reporting a decrease in their CS dispensing since HB1, the main reason given for this decrease was “they receive fewer CS prescriptions from prescribers since HB1” (36.7%). Other prominent reasons for those reporting a decrease in CS dispensing were “policy changes in my pharmacy” (18.2%) and “implementation of HB1 requiring mandated use of KASPER” (19.6%). For those pharmacists reporting a change in dispensing since HB1, almost 40% indicate a positive impact on their ability to manage their patients while 46% indicate no change in their ability to manage patients as a result of HB1.

Impact of HB1 on Doctor-Shopping Behavior

When questioned about suspicions of doctor shopping and/or diverting, most pharmacists (66.5%) indicated they had suspected between 1 and 20 patients of these behaviors during the time period since HB1. About one-fifth (21.6%) reported they had suspected no patients of doctor-shopping behavior while just over 10% (11.9%) reported suspecting more than 20 patients of doctor-shopping behavior. Although the majority (58.5%) perceives their suspicions about doctor-shopping patients have not changed since HB1, over one-fourth (26.2%) perceive they suspect fewer patients of doctor shopping since HB1.

Dismissal/Referral of Patients

Overall, the vast majority (92%) of pharmacist respondents indicate they do not refer patients to substance abuse treatment. Of the few (6.3%) who reported referring 1 – 5 patients to treatment since implementation of HB1, almost all (96%) indicate their referring behavior has not changed since implementation of HB1.

Effectiveness of KASPER

Overall, pharmacist respondents believe KASPER is effective at reducing abuse and diversion (77.2%) and reducing doctor shopping (81.9%). The full results of the pharmacist survey are presented in Appendix VI.

3. Law Enforcement

Although HB1 had no direct impact on law enforcement registrants of KASPER, this category of registrants was also surveyed to identify perceived impact of HB1 and

effectiveness of KASPER. The majority of law enforcement respondents were city/county law enforcement (40%), followed by state law enforcement (25.8%) and other (21.3%) and report using a mean of 2.4 KASPER reports in the past month.

Use and Interpretation of KASPER Reports

In general, the majority of law enforcement respondents indicate using the information in KASPER reports to confirm/support their decisions to pursue investigation (60%) while 30% indicate using reports to confirm/support their decisions to dismiss investigations. Almost all are confident in the accuracy of information in a KASPER report (94%) and in their ability to interpret the information in a KASPER report (96%).

Impact of HB1

When questioned about the impact and effectiveness of HB1, law enforcement respondents report little change in the number and types of cases they investigate and little change in communication with pharmacists and prescribers since implementation of HB1. The majority (62%) perceives that prescribers have altered their prescribing of CS since HB1, while less than one-half (44.6%) perceive pharmacists to have altered their stocking and dispensing of CS.

Effectiveness of KASPER

Overall, law enforcement respondents believe KASPER is more effective at reducing doctor-shopping (84.3%) than abuse and diversion (70.1%) with over two-thirds (69.9%) of respondents indicating that there has been a decrease in doctor-shopping behavior as a result of HB1.

The full results of the law enforcement survey are presented in Appendix VI.

C. Project 2 Summary

The results from the qualitative studies suggest that although initial confusion and disruptions to workflow were evident as a result of HB1, those have largely been resolved and, for the most part, have not negatively impacted health care professional practices. It should be noted however, that a minority of prescribers indicate they no longer prescribe CS, or prescribe fewer CS, as a result of the HB1 mandate and its burden on their practices.

Prescribers utilize significantly more KASPER reports in their practice than pharmacists. This is not surprising in that while HB1 required pharmacists to register with KASPER, they have no statutory mandate to utilize the KASPER system. This qualitative information is in line with the quantitative analysis of KASPER queries presented in Project 1, which show a significant increase in registrations by pharmacists in July 2012,

but a much smaller change in queries made by pharmacists post-HB1.

More pharmacists than prescribers perceive the information in KASPER reports as accurate and more pharmacists are confident in their ability to accurately interpret the information in KASPER reports. These results are likely explained by the fact that pharmacists are more familiar with how dispensing data is presented than their prescriber counterparts by virtue of practicing in pharmacies.

Prescribers discuss KASPER reports with patients and other health care providers more frequently than do pharmacists, and a significant number of respondents in both groups perceive they discuss KASPER reports with patients more frequently since the passage of HB1. This observation may be a direct result of the statutory changes in HB1 that authorized providers to discuss and provide copies of reports to patients and allowed them to be shared with other health care providers and placed in medical charts. The initial KASPER statutes precluded the sharing of reports in these manners.

Additionally, the majority of prescriber and pharmacist respondents report little change in prescribing and dispensing habits since implementation of HB1, although they perceive their prescribing and dispensing behaviors to be monitored more closely. Both prescribers and pharmacists refer few patients to substance treatment and HB1 has not impacted their referrals. Information gleaned from the stakeholder interviews, coupled with the survey findings suggest substance abuse treatment may be an area where additional policy interventions are warranted.

Overall, prescribers, pharmacists and law enforcement believe KASPER to be more effective at reducing doctor shopping than reducing the abuse and diversion of prescription drugs. Interestingly, when compared to results from a survey of KASPER registrants conducted in an evaluation of the KASPER program conducted in 2010,¹³ the perceptions relative to effectiveness have diverged somewhat. For example, in 2010 each group of respondents viewed KASPER as equally effective in reducing abuse and diversion, and doctor shopping. In the present study, fewer respondents in each group perceive KASPER as effective compared to 2010, and they perceive greater effectiveness of KASPER at reducing doctor shopping relative to abuse and diversion. The perception that KASPER is more effective at reducing doctor-shopping than overall abuse and diversion may be a direct result of the impact of mandatory registration and use of KASPER, as evidence from both qualitative studies suggest doctor-shopping has diminished as a result of HB1.

¹³ Independent Evaluation of the Impact and Effectiveness of the Kentucky All Schedule Prescription Electronic Reporting Program (KASPER). Available at <http://www.chfs.ky.gov/NR/rdonlyres/24493B2E-B1A1-4399-89AD-1625953BAD43/0/KASPERevaluationFinalReport10152010.pdf>; last accessed 3-14-15.

VI. Project 3: Changes in Prescriber Behavior, Patient Behavior and Outcomes

Multiple approaches were taken to analyze the impact of HB1 on prescriber behavior, patient behavior (e.g., doctor-shopping) and health outcomes, including morbidity and mortality from prescription drug overdose in Kentucky. The KASPER administrative dataset utilized for Project 3 contained CS prescription data from July 1, 2009 through December 31, 2013 and included the following information for each CS prescription record:

- 1) Patient identifier (Social Security Number)
- 2) Patient last name
- 3) Patient first name
- 4) Patient postal address information including city, state and zip code
- 5) Patient date of birth
- 6) Patient gender
- 7) Prescription number
- 8) Prescriber DEA number
- 9) Date written
- 10) Refills authorized
- 11) Refill number
- 12) Dispenser DEA number
- 13) National Drug Code (NDC number)
- 14) Quantity dispensed
- 15) Days supply

Prior to transfer of the dataset, unique patients were identified by CHFS through a clustering process that links prescriptions for patients via an assigned cluster ID.¹⁴ After the clustering process was applied and data transferred, identifying patient information (name, SSN, date of birth, address) in the dataset was removed by an honest broker prior to transfer to the research team for analysis. At no time did the HB1 evaluation team have access to identifiable patient-specific information.

The de-identified dataset was linked to the DEA registrant file to identify unique prescribers and unique pharmacies based on DEA registration number. Finally, data from publically available datasets, including the Substance Abuse and Mental Health Services Administration's Treatment Episode Dataset (TEDS) and the Centers for Disease Control and Prevention (CDC) were used to describe population level

¹⁴ Jean Hall. Linking Patients in PDMP Data. PDMP Training & Technical Assistance Center Webinar, October 15, 2014. Available at http://www.pdmpassist.org/pdf/TTAC_Linking_Patients_in_PDMP_Data_20141015.pdf; last accessed 3-15-14.

outcomes relative to substance abuse and overdose in Kentucky and surrounding states.

Specific details related to the datasets utilized are provided in Appendix VII. Project 3 was approved by both the CHFS IRB and the University of Kentucky IRB.

A. Characterizing the KASPER Dataset

To address the aims in Project 3, the research team began by characterizing the KASPER dataset, including the numbers of unique patients and pharmacies, and the number and type of unique prescribers, for the study period (FY 2010 to FY 2013). The number of unique patients, prescribers and pharmacies in the KASPER database for the study period are presented in Table 9. Of note, the number of unique prescribers in the KASPER database decreased by 14% between FY 2012 and FY2013, the time period in which HB1 was implemented (July 2012). The number of unique patients in the KASPER database decreased each year, with a 7% decrease noted between FY 2012 and FY 2013. The number of unique pharmacies in the KASPER database was more varied across the study period, with an almost 10% increase observed between FY 2011 and FY 2012, followed by a 2.5% decrease between FY 2012 and FY 2013.

**Table 9: Number of Patients, Prescribers and Pharmacies in KASPER Dataset
FY 2010 to FY 2013**

	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Number of unique prescribers	58,424	10.52%	64,570	0.56%	64,932	-14.25%	55,685
Number of unique patients	1,806,995	-0.70%	1,794,290	-1.03%	1,775,767	-7.00%	1,651,440
Number of unique pharmacies	1,528	-0.33%	1,523	9.85%	1,673	-2.75%	1,627
Mean number of unique patients per prescriber	63.37	-9.53%	57.33	0.65%	57.70	2.86%	59.35
Significantly different from FY 2013 post HB1	Yes P=0.003		No P=0.119		No P=0.214		
Mean number of unique patients per pharmacy	2,423.1	0.31%	2,430.6	-7.87%	2,239.3	-9.29%	2,031.3
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P=0.016		

Source: Cabinet for Health and Family Services, KASPER administrative dataset

The mean number of unique patients per prescriber decreased by 9.5% between FY 2010 and FY 2011, remained relatively unchanged between FY 2011 and FY 2012, then increased by almost 3% in the post-HB1 period. The mean number of unique patients per pharmacy decreased significantly (7.9%) between FY 2011 and FY 2012 and decreased again (9.3%) between FY 2012 and FY 2013. These observations

support the qualitative evidence gleaned from the stakeholder interviews and survey of KASPER registrants (see Project 2) that some prescribers have stopped prescribing CS in Kentucky post-HB1. It is interesting to note that of the unique prescribers in the KASPER dataset, the majority is classified as out of state based on the address associated with their DEA registration. To determine if HB1 was associated with a chilling effect on Kentucky prescribers specifically, the number of unique Kentucky prescribers (Table 10) and the total number CS prescriptions (Table 11) attributed to them over the study period were compared to those practicing out of state. At any given time throughout the study period, of the unique prescribers in the dataset almost two-thirds are identified as out of state prescribers based on their DEA registration (Table 10) and these prescribers, on average, issue only about 10% of the CS prescriptions dispensed and reported to KASPER (Table 11). In contrast, the approximately 14,000 – 15,000 unique Kentucky prescribers identified in the dataset each fiscal year, issued over 10,000,000 CS prescriptions or about 90% of the total CS prescriptions reported to KASPER (Table 11). Interestingly, the number of unique Kentucky prescribers increased each fiscal year studied. Although individual prescribers may have opted out of prescribing CS post-HB1 as suggested in Project 2, overall, the number of Kentucky prescribers issuing CS did not decline.

Table 10: Number and Percent of Prescribers by Prescriber Location in Kentucky, Out-of-State and Not Matched: KASPER, FY 2010 to FY 2013

	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Kentucky	13,851	3.09%	14,279	3.54%	14,784	2.31%	15,125
Percent of total prescribers	23.71%		22.11%		22.77%		27.16%
Out-of-state	35,805	19.15%	42,660	1.84%	43,445	-17.43%	35,872
Percent of total prescribers	61.28%		66.07%		66.91%		64.42%
DEA Not Matched	8,768	-12.97%	7,631	-12.16%	6,703	-30.06%	4,688
Percent of total prescribers	15.01%		11.82%		10.32%		8.42%
Total	58,424	10.52%	64,570	0.56%	64,932	-14.24%	55,685

Table 11 : Number and Percent of Prescriptions by Prescriber Location in Kentucky, Out-of-State and Not Matched: KASPER, FY 2010 to FY 2013

	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Kentucky	10,156,195	3.03%	10,463,775	3.00%	10,777,879	-4.93%	10,246,586
Percent of total prescriptions	88.23%		88.73%		89.24%		90.68%
Out-of-state	1,237,757	0.07%	1,238,587	-0.24%	1,235,663	-17.67%	1,017,343
Percent of total prescriptions	10.75%		10.50%		10.23%		9.00%
DEA Not Matched	117,394	-23.45%	89,868	-29.07%	63,739	-42.90%	36,393
Percent of total prescriptions	1.02%		0.76%		0.53%		0.32%
Total	11,511,346	2.44%	11,792,230	2.42%	12,077,281	-6.43%	11,300,322

As prescriber data in the KASPER dataset were limited to the prescriber DEA number submitted by pharmacies, the DEA registrant file was used to identify prescribers by prescriber type as defined by the DEA.¹⁵ ‘Practitioner’ registrants include physicians, dentists, veterinarians and podiatrists authorized to prescribe, dispense and administer CS. ‘Nurse practitioner’ registrants are mid-level practitioners authorized to prescribe CS, and the category of ‘other practitioner’ includes hospital and clinic practitioners, physician assistants¹⁶ and optometrist registrants who are authorized to prescribe CS. Table 12 presents the number of prescriber registrants by prescriber type in the KASPER database for the study period and Table 13 shows prescriber type classified by in-state or out-of-state addresses for the study period.

¹⁵ National Technical Information Service, U.S. Department of Commerce, “Active Controlled Substances Act (CSA) Registrants Database: Drug Enforcement Administration, Quarterly DEA File.” 2014. <http://www.ntis.gov/products/dea/>

¹⁶ Physician Assistants (PAs) are from out-of-state. PAs are not authorized to prescribe CS in Kentucky.

Table 12: Number of Prescribers by Prescriber Type: KASPER, FY 2010 to FY 2013

Prescriber type	FY 2010			FY 2011			FY 2012			FY 2013		
	Count	Percent change (FY10-11)	Count	Count	Percent change (FY11-12)	Count	Count	Percent change (FY12-13)	Count	Count	Percent change (FY12-13)	Count
Practitioner ¹	44,206	13.45%	50,153	1.04%	50,677	-13.22%	43,976					
Nurse practitioner ²	2,960	36.32%	4,035	16.98%	4,720	-3.86%	4,538					
Other practitioner ³	1,583	17.31%	1,857	5.82%	1,965	-8.19%	1,804					
Prescriber type not matched ⁴	9,675	-11.89%	8,525	-11.20%	7,570	-29.10%	5,367					
Total	58,424	10.52%	64,570	0.56%	64,932	-14.24%	55,685					

¹ Practitioners are predominately physicians, dentists, veterinarians and podiatrist who are authorized to prescribe, dispense, and administer controlled substances.

² Nurse practitioners are mid-level practitioners who are authorized to prescribe controlled substances.

³ Other practitioners includes hospital and clinic practitioners, physician assistants and optometrists.

⁴ Prescriber DEA number reported did not match DEA registrant file

Of the over 55,000 unique prescribers in the KASPER database each year, the vast majority (76-79%) are classified as ‘practitioners’ (Table 12). It is interesting to note that of the 43,976 unique ‘practitioners’ prescribing CS, only 12,733 were classified as in-state prescribers based on the address affiliated with their DEA registrant number (Table 13). In FY 2010, 5% of the unique prescribers in the KASPER dataset were identified as ‘nurse practitioners.’ The number of ‘nurse practitioners’ as a percent of the prescriber population increased each year of the study period to a high of over 8% in FY 2013. Similarly, a large proportion of the unique ‘nurse practitioners’ in 2013 were out of state, with 2,995 of the 4,538 that prescribed a CS reported to KASPER identified as out of state prescribers (Table 13).

Table 13: Prescriber Types by Kentucky and Out-of-State¹: KASPER, FY 2010 to FY 2013

	FY 2010			FY2011			FY2012			FY 2013		
	Out of state		Total									
	In state	state		In state	state		In state	state		In state	state	
Practitioner ²	11,977	32,229	44,206	12,264	37,889	50,153	12,532	38,145	50,677	12,734	31,242	43,976
Nurse practitioner ³	961	1,999	2,960	1,126	2,909	4,035	1,334	3,386	4,720	1,543	2,995	4,538
Other practitioner ⁴	465	1,118	1,583	434	1,423	1,857	414	1,551	1,965	386	1,418	1,804
DEA Not Matched	448	9,227	9,675	455	8,070	8,525	504	7,066	7,570	462	4,905	5,367

¹ Out-of-state also includes records where no state was available.

² Practitioners are predominately physicians, dentists, veterinarians and podiatrist who are authorized to prescribe, dispense, and administer controlled substances.

³ Nurse practitioners are mid-level practitioners who are authorized to prescribe controlled substances.

⁴ Other practitioners includes hospital and clinic practitioners, physician assistants and optometrists.

As further evidence supporting improvement in data quality submitted by pharmacies, the number of prescribers who do not match the DEA registrant file decreases significantly throughout the study period, from a high of over 16% to less than 10% in FY 2013. Tables summarizing the distribution of prescribers by type and region can be found in Appendix VIII.

Should practitioners who previously prescribed CS make a decision to no longer prescribe CS, a concern often expressed is that patients who have a legitimate medical need for a CS will have difficulty accessing them. The fact that a 7% decrease in the number of unique patients in the KASPER dataset (Table 9) is noted in the time period following implementation of HB1 warrants further study, as this decrease could be due to prescribers making different treatment decisions for patients instead of prescribing a CS, or could be due to the elimination of doctor-shopping patients, both of which are desired outcomes of HB1. Alternatively, this observation could be due to an access issue secondary to a chilling effect of HB1, which negatively impacts patients. We continue to evaluate the data for evidence of a chilling effect throughout Project 3.

B. CS Prescriptions by Prescriber Type

To assess changes in the number of CS prescriptions dispensed by prescriber type over the study period, the total number of CS prescriptions dispensed by prescriber type and the mean number of CS dispensed per prescriber were calculated for FY 2010 to FY 2013 and results are depicted in Tables 14 and 15.

Table 14: Total Number of Prescriptions Dispensed by Prescriber Type: KASPER, FY 2010 to FY 2013

Prescriber type	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Practitioner ¹	10,870,469	1.94%	11,080,889	1.30%	11,224,954	-7.68%	10,362,839
Nurse practitioner ²	398,350	25.24%	498,889	35.56%	676,296	16.47%	787,672
Other practitioner ³	26,570	-3.51%	25,638	2.39%	26,251	9.15%	28,653
DEA not matched ⁴	215,806	-13.44%	186,792	-19.83%	149,756	-19.10%	121,158
Total	11,511,195	2.44%	11,792,208	2.42%	12,077,257	-6.43%	11,300,322

¹ Practitioners are predominately physicians, dentists, veterinarians and podiatrist who are authorized to prescribe, dispense, and administer controlled substances.

² Nurse practitioners are mid-level practitioners who are authorized to prescribe controlled substances.

³ Other practitioners includes hospital and clinic practitioners, physician assistants and optometrists.

⁴ Prescriber DEA number reported did not match DEA registrant file.

Increasing numbers of CS prescriptions dispensed are attributed to ‘nurse practitioners’ each year of the study period, with almost 400,000 total prescriptions attributed to this group in FY 2010 increasing to almost 800,000 prescriptions in FY 2013 (Table 14). Kentucky law first authorized Advanced Practice Registered Nurses (APRNs) to prescribe CS in 2006.¹⁷ Since that time, increasing numbers of APRNs have become licensed to practice in Kentucky, from just fewer than 2,500 in FY 2010 to over 3,700 in FY 2013.¹⁸ The increasing numbers of CS prescriptions attributed to ‘nurse practitioners’ could be due to increased numbers of DEA-registered APRNs prescribing CS under a “Collaborative Agreement for the Advanced Practice Registered Nurse’s Prescriptive Authority for Controlled Substances” (CAPA-CS) or could be due to individual APRNs prescribing increased numbers of CS.

In contrast to APRNs, the total number of CS prescriptions attributed to ‘practitioners’ as defined by the DEA decreased by over 7% between FY 2012 and FY 2013 following implementation of HB1. It is important to note that, as a group, ‘nurse practitioners’ issue very few of the total CS prescriptions dispensed and reported to KASPER, ranging from 3.5% in FY 2010 to 7% in FY 2013. Thus, almost all (over 90% in each FY studied) of the CS prescriptions dispensed and reported to KASPER are attributed to ‘practitioners.’ Overall, as described in Project 1 (Table 1), an over 6% decrease in CS dispensing was noted in the post-HB1 period.

Table 15: Mean Number of Prescriptions Dispensed per Prescriber by Prescriber Type: KASPER, FY 2010 to FY 2013

Prescriber type	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Practitioner ¹	245.90	-10.15%	220.94	0.25%	221.50	6.39%	235.65
Nurse practitioner ²	134.58	-8.13%	123.64	15.89%	143.28	21.14%	173.57
Other practitioner ³	16.78	-17.75%	13.81	-3.24%	13.36	18.89%	15.88

¹ Practitioners are predominately physicians, dentists, veterinarians and podiatrist who are authorized to prescribe, dispense, and administer controlled substances.

² Nurse practitioners are mid-level practitioners who are authorized to prescribe controlled substances.

³ Other practitioners includes hospital and clinic practitioners, physician assistants and optometrists.

¹⁷ KRS 314.042 License to practice as an advanced practice registered nurse --Application -- Renewal -- Reinstatement -- Use of "APRN" – Prescriptive authority under CAPA-NS and CAPA-CS -- Exemption from CAPA-NS requirement. Available at <http://www.lrc.ky.gov/Statutes/statute.aspx?id=42980>; last accessed 3-11-15.

¹⁸ Kentucky Board of Nursing Annual Report 2012-2103. Available at <http://kbn.ky.gov/Documents/Annual%20Reports/annrpt1213.pdf>; last accessed 3-11-15.

The mean number of CS prescriptions per prescriber decreased for all categories of prescribers between FY 2010 and FY 2011 (Table 15). In FY 2012, the category of ‘nurse practitioners’ prescribed a mean of 143 CS prescriptions, which increased in FY 2013 to a mean of 173. For the ‘practitioner’ category, the mean number of prescriptions dispensed increased from a mean of 221 to a mean of 236 between FY 2012 and FY 2013. These changes in means per prescriber, coupled with the decreases observed in numbers of unique out of state prescribers in the KASPER database (Table 10) suggest that although there are fewer prescribers issuing CS prescriptions, the prescribers who issue CS are issuing more CS prescriptions in the post-HB1 period than they were prior to HB1. This observation argues against a blanket chilling effect of HB1 as patients who have legitimate need appear to be accessing CS therapy as evidenced by increase in mean number of prescriptions issued by prescribers post-HB1.

To assess for preferential impacts of HB1 on prescribing of drugs by Schedule, class or for individual select drugs within a class, the number of prescriptions dispensed for these groups by prescriber type were further analyzed. Table 16 depicts the total number of prescriptions dispensed by prescriber type and CS Schedule. The increases in CS prescriptions dispensed attributed to ‘nurse practitioners’ are distributed across all Schedules of CS, ranging from 12-22%. Similarly, the decrease in CS prescriptions dispensed and attributed to ‘practitioners’ post HB1 is distributed across all Schedules, ranging from 4.7% for Schedule II and 8.25% for Schedule IV.

Table 16: Total Number of Prescriptions Dispensed by Selected Prescriber Type and Schedule: KASPER, FY 2010 to FY 2013

Type	Drug class	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Practitioner								
	Schedule II	1,998,950	8.45%	2,167,794	6.58%	2,310,514	-4.70%	2,201,988
	Schedule III	3,769,305	4.01%	3,920,638	3.11%	4,042,740	-7.47%	3,740,868
	Schedule IV	4,507,402	-1.24%	4,451,611	-1.50%	4,384,927	-8.25%	4,023,118
	Schedule V	431,355	-4.30%	412,823	-11.29%	366,216	-6.90%	340,945
Nurse practitioner								
	Schedule II	40,994	22.76%	50,323	29.53%	65,183	21.76%	79,366
	Schedule III	122,084	34.38%	164,061	45.38%	238,520	17.82%	281,030
	Schedule IV	196,259	23.05%	241,503	36.89%	330,604	14.90%	379,857
	Schedule V	26,194	25.13%	32,776	4.07%	34,110	11.68%	38,093
Other practitioner								
	Schedule II	7,386	1.22%	7,476	2.80%	7,685	9.69%	8,430
	Schedule III	8,504	-3.62%	8,196	7.81%	8,836	10.24%	9,741
	Schedule IV	7,401	3.23%	7,640	-4.01%	7,334	10.14%	8,078
	Schedule V	2,226	-12.76%	1,942	3.04%	2,001	-3.05%	1,940

Tables 17a and 17b present the total number and mean number, respectively, of CS prescriptions dispensed by prescriber type and drug class for opioids, benzodiazepines and stimulants. In FY 2013 following implementation of HB1 in July 2012, ‘practitioners’ as a group issued 9% fewer benzodiazepines and 10% fewer opioid prescriptions than they did in FY 2012. In contrast, as a group, ‘nurse practitioners’ issued almost 10% more opioid prescriptions and just over 20% more benzodiazepine prescriptions than they did in FY 2012. Both ‘practitioners’ and ‘nurse practitioners’ issued more stimulant prescriptions in FY 2013 than in FY 2012 (Table 17a).

Table 17a: Total Number of Prescriptions Dispensed by Prescriber Type and Drug Class: KASPER, FY 2010 to FY 2013

Type	Drug class	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Practitioner								
	Opioid	6,043,579	1.37%	6,126,622	0.96%	6,185,258	-10.00%	5,566,430
	Benzodiazepine	2,586,995	1.96%	2,637,797	0.55%	2,652,242	-8.97%	2,414,388
	Stimulant	946,068	7.59%	1,017,911	4.68%	1,065,514	7.59%	1,146,427
Nurse practitioner								
	Opioid	205,564	22.67%	252,169	31.70%	332,101	9.86%	364,854
	Benzodiazepine	82,348	31.26%	108,091	52.19%	164,506	20.82%	198,763
	Stimulant	49,361	32.56%	65,435	33.36%	87,266	26.35%	110,261
Other practitioner								
	Opioid	17,807	-3.35%	17,211	3.03%	17,733	6.08%	18,812
	Benzodiazepine	3,723	5.56%	3,930	2.90%	4,044	18.10%	4,776
	Stimulant	1,612	-3.78%	1,551	4.90%	1,627	-5.72%	1,534

The mean number of opioid prescriptions per prescriber attributed to ‘practitioners’ decreased by just over 2% in the post-HB1 period, whereas the mean number of benzodiazepine and mean number of stimulant prescriptions per prescriber increased in the post-HB1 period (Table 17b). The mean number of prescriptions per prescriber attributed to ‘nurse practitioners’ increased for all 3 drug classes studied in the post HB1 period. For ‘practitioners,’ a decrease in total prescriptions, coupled with an increase in the mean number of prescriptions per practitioner for the benzodiazepine class, suggests that benzodiazepine prescribing is concentrating in fewer prescribers.

Table 17b: Mean Number of Prescriptions Dispensed per Prescriber by Selected Prescriber Type and Drug Class: KASPER, FY 2010 to FY 2013

Type	Drug class	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Practitioner								
	Opioid	183.59	-3.04%	178.01	0.61%	179.10	-2.18%	175.20
	Benzodiazepine	117.61	-11.18%	104.46	-0.18%	104.27	5.82%	110.34
	Stimulant	99.21	-5.41%	93.84	0.15%	93.98	25.35%	117.80
Nurse practitioner								
	Opioid	94.56	4.71%	99.01	12.22%	111.11	1.60%	112.89
	Benzodiazepine	49.91	-2.62%	48.60	25.64%	61.06	28.15%	78.25
	Stimulant	61.70	-3.50%	59.54	9.37%	65.12	28.96%	83.98
Other practitioner								
	Opioid	14.56	-10.23%	13.07	-0.69%	12.98	8.55%	14.09
	Benzodiazepine	7.12	-8.57%	6.51	-7.22%	6.04	34.27%	8.11
	Stimulant	8.96	-15.51%	7.57	-8.59%	6.92	28.18%	8.87

Tables summarizing the total numbers and mean numbers of prescriptions dispensed by prescriber type and select drug for selected opioids, benzodiazepines and stimulants are provided in Appendix IX.

The growth in total prescriptions and mean number of prescriptions issued by ‘nurse practitioners’ coupled with the changes in prescribing observed for the ‘practitioner’ category may indicate that APRNs in Kentucky play a role in ensuring adequate access to needed CS therapy.

C. CS Prescribing at the Patient Level

To expand on Project 1 results and focus on the patient level impact of HB1, unique patients identified by county codes as Kentucky residents were further evaluated. Analysis included the total number of CS prescriptions dispensed per patient and per capita and the mean number of CS prescriptions dispensed per patient by 1) Schedule; 2) select drug class; and 3) individual select drugs. Drug classes selected were as previously described in Project 1. These three analyses were conducted to determine if HB1 preferentially impacted prescribing and dispensing of one Schedule or one drug class over others, and to determine if HB1 selectively impacted the prescribing and dispensing of specific drugs within each class at the patient level.

1. Prescribing at Patient Level by Schedule

Similar to results presented in Project 1 (Table 1), the total number of CS prescriptions dispensed in Kentucky decreased for the first time since the inception of KASPER data collection, with an almost 6% decrease in the number of prescriptions written for Kentucky patients observed (Table 18).

Table 18: Number of Controlled Substance Prescriptions per Patient and Per Capita: Kentucky Residents, FY 2010 to FY 2013

	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Number of prescriptions to Kentucky residents	10,909,431	2.58%	11,190,370	2.63%	11,484,495	-5.31%	10,875,043
Number of unique patients in Kentucky	1,688,460	-1.48%	1,663,198	-1.04%	1,646,162	-6.38%	1,541,199
Prescriptions per capita (annual estimates of population)	2.51	2.10%	2.56	2.31%	2.62	-5.65%	2.47
Average number of prescriptions per patient	6.46	4.13%	6.73	3.69%	6.98	1.14%	7.06
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		

Source: Cabinet for Health and Family Services, KASPER administrative dataset; U.S. Census Bureau, Population Division Release Date: December 2014

Similar to the data presented in Table 1 (Project 1) for all unique patients in the KASPER database (Kentucky residents and out of state), the number of unique patients decreased each year of the study period, with a 6.4% decrease noted in the post-HB1 period. When normalized on a per capita basis, the number of prescriptions dispensed per capita decreased by over 5% in the post-HB1 period (Table 18). Interestingly, the average number of CS prescriptions per patient increased from 6.98 in FY 2012 to 7.06 in FY 2013. Taken together, these data suggest that the over 5% drop in the number of prescriptions dispensed to Kentucky residents is due to the drop in the number of unique patients receiving a prescription for a CS in Kentucky. The patients remaining in the database continue to receive an average of 7 prescriptions per year. If patients with legitimate medical need for CS therapy were having difficulty accessing CS, one would anticipate a decrease in the mean number of prescriptions per patient. The fact that the mean number of prescriptions per patient is increasing suggests that the loss of unique patients from KASPER may be those who did not have a legitimate need for CS therapy; therefore, prescribers are either making alternative treatment decisions or those who were possibly 'doctor-shopping' may no longer be doing so.

Data on the mean number of CS prescriptions per patient dispensed by Schedule for the study period are depicted in Table 19. In contrast to the decrease in the total number of prescriptions dispensed that was observed for all Schedules (Project 1, Table 1), the mean number of Scheduled prescriptions dispensed per patient across the study period increased for all Schedules with the exception of Schedule V. Specifically, the mean number of Schedule II and Schedule III per patient continued to increase in the post-HB1 study period (FY 2013) compared to FY 2012, as it had in earlier years, although the rate of increase was lower than in previous years. The mean number of Schedule IV prescriptions per patient has remained relatively unchanged over the study period. Schedule V prescriptions, mainly represented by prescriptions for codeine-containing cough syrups, are more variable with an almost 10% decrease in mean number of prescriptions per patient between FY 2011 and FY 2012, and a slight increase of almost 1% between FY 2012 and FY 2013.

Table 19: Mean Number of Prescriptions Per Patient by Schedule: KASPER, FY 2010 to FY 2013

Schedule dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Schedule II	1.15	8.70%	1.25	8.00%	1.35	2.96%	1.39
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		
Schedule III	2.20	5.91%	2.33	5.58%	2.46	1.63%	2.50
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		
Schedule IV	2.65	0.38%	2.66	0.75%	2.68	0.00%	2.68
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		No P=0.772		
Schedule V	0.259	-2.32%	0.253	-9.49%	0.229	0.87%	0.231
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P=0.028		

Source: Cabinet for Health and Family Services, KASPER administrative dataset

2. Prescribing at the Patient Level by Drug Class and Select Drugs

Data on the mean number of CS prescriptions per patient dispensed by drug class for FY 2010 through FY 2013 are presented in Table 20. Similar to the pattern observed for total numbers of prescriptions dispensed by drug class described in Project 1 (Table 2), the mean number of opioid prescriptions and benzodiazepine prescriptions per patient decreased, while the mean number of stimulant prescriptions per patient increased over the study period. Specifically, the mean number of opioid prescriptions per patient decreased by 2% (from 3.74 to 3.66) between FY 2012 and FY 2013 while the mean number of benzodiazepine prescriptions per patient decreased slightly (1.6 to 1.59; <1%) in the post HB1 period. Prior to HB1, the mean number of prescriptions per patient for opioids and benzodiazepines had been increasing by 2-3% per year. In contrast, the mean number of stimulant prescriptions per patient increased in all years of the study period, from a low of 8.2% (FY 2011 to FY 2012) to a high of over 16% (0.66 to 0.77) between FY 2012 and FY 2013.

Table 20: Mean Number of Prescriptions Dispensed Per Patient by Drug Class: KASPER, FY 2010 to FY 2013

Drug class dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Mean number of opioids prescriptions per patient	3.54	2.54%	3.63	3.03%	3.74	-2.14%	3.66
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		
Mean number of benzodiazepine prescriptions per patient	1.51	2.65%	1.55	3.23%	1.60	-0.63%	1.59
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P=0.006		
Mean number of stimulant prescriptions per patient	0.56	8.93%	0.61	8.20%	0.66	16.67%	0.77
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Tables 21a, b, and c show the mean number of prescriptions per patient for these select opioids throughout the study period. These opioids were selected based on their history of abuse in Kentucky (oxycodone, hydrocodone, oxymorphone, methadone, tramadol); their prevalence of use in treating cancer pain to assess for possible chilling effect (morphine, fentanyl); and buprenorphine products used for medication-assisted treatment of opioid addiction.

Table 21a: Mean Number of Opioid Prescriptions Dispensed per Patient by Selected Drugs: KASPER, FY 2010 to FY 2013

Selected drugs dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Hydrocodone	1.97	4.06%	2.05	2.93%	2.11	-6.64%	1.97
Significantly different from FY 2013 post HB1	No P=0.874		Yes P<0.001		Yes P<0.001		
Oxycodone	0.50	14.00%	0.57	8.77%	0.62	-4.84%	0.59
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		
Hydromorphone	0.014	14.29%	0.016	6.25%	0.017	5.88%	0.018
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P=0.005		
Oxymorphone	0.009	33.33%	0.012	33.33%	0.016	-31.25%	0.011
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Table 21b: Mean Number of Opioid Prescriptions Dispensed per Patient by Selected Drugs: KASPER, FY 2010 to FY 2013

Selected drugs dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Fentanyl	0.051	0.00%	0.051	5.88%	0.054	3.70%	0.056
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P=0.032		
Morphine	0.067	2.99%	0.069	11.59%	0.077	10.39%	0.085
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		
Buprenorphine - Total	0.102	25.49%	0.128	55.47%	0.199	47.74%	0.294
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		
Buprenorphine and naloxone combination only	0.096	22.92%	0.118	46.61%	0.173	51.45%	0.262
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Table 21c: Mean Number of Opioid Prescriptions Dispensed per Patient by Selected Drugs: KASPER, FY 2010 to FY 2013

Selected drugs dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Methadone	0.044	2.27%	0.045	4.44%	0.047	0.00%	0.047
Significantly different from FY 2013 post HB1	Yes P=0.001		Yes P=0.004		No P=0.960		
Codeine	0.200	-3.50%	0.193	-11.40%	0.171	6.43%	0.182
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		
Tramadol	0.316	12.03%	0.354	6.78%	0.378	-5.82%	0.356
Significantly different from FY 2013 post HB1	Yes P<0.001		No P=0.322		Yes P<0.001		

Source: Cabinet for Health and Family Services, KASPER administrative dataset

The mean number of prescriptions dispensed per patient decreased significantly for hydrocodone (-6.6%), oxycodone (-4.8%) and oxymorphone (-31.3%) between FY 2012 and FY 2013 (Table 21a) and for tramadol (-5.8%, Table 21c). The mean number of prescriptions dispensed per patient for the other select opioid drugs studied all increased throughout the study period with the greatest increase noted in the mean number of prescriptions per patient for buprenorphine/buprenorphine-naloxone combinations (Table 21b).

The mean number of benzodiazepine prescriptions dispensed per patient for the study period are shown in Table 22. The mean number of prescriptions dispensed per patient decreased significantly for alprazolam (-4%) and diazepam (-2.7%) between FY 2012 and FY 2013. In contrast, the mean number of prescriptions dispensed per patient for clonazepam increased by 4.4% following HB1 implementation.

Table 22: Mean Number of Benzodiazepine Prescriptions Dispensed per Patient by Selected Drugs: KASPER, FY 2010 to FY 2013

Selected drugs dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Alprazolam	0.570	5.26%	0.600	0.67%	0.604	-3.97%	0.580
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		
Diazepam	0.255	1.18%	0.258	2.33%	0.264	-2.65%	0.257
Significantly different from FY 2013 post HB1	No P=0.303		No P=0.515		Yes P<0.001		
Clonazepam	0.316	6.65%	0.337	6.82%	0.360	4.44%	0.376
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Table 23 shows the mean number of stimulant prescriptions dispensed per patient for the selected stimulants. The mean number of stimulant prescriptions dispensed per patient increased throughout the study period for all stimulants with the exception of dextroamphetamine, which decreased by 14.3% in the post-HB1 period. As discussed in Project 1, dextroamphetamine was in short supply during 2012, which may have contributed to the changes observed in dextroamphetamine prescriptions post-HB1.

Table 23: Mean Number of Stimulant Prescriptions Dispensed per Patient by Selected Drugs: KASPER, FY 2010 to FY 2013

Selected drugs dispensed	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Mixed amphetamine salts	0.139	8.63%	0.151	11.26%	0.168	20.24%	0.202
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		
Dextroamphetamine	0.007	0.00%	0.007	0.00%	0.007	-14.29%	0.006
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P=0.002		
Lisdexamfetamine	0.083	19.28%	0.099	9.09%	0.108	11.11%	0.120
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		
Methylphenidate	0.169	5.33%	0.178	6.18%	0.189	14.29%	0.216
Significantly different from FY 2013 post HB1	Yes P<0.001		Yes P<0.001		Yes P<0.001		

Source: Cabinet for Health and Family Services, KASPER administrative dataset

Taken together, these results suggest that HB1 preferentially impacts CS prescribing at the patient level for classes of drugs and for specific drugs within each class, similar to what was noted in the analysis of total aggregate prescribing in Project 1. The fact that the mean number of prescriptions for oxycodone, hydrocodone and oxymorphone - three specific opioids associated with abuse and diversion in Kentucky - decreased in the post-HB1 period while the mean number of prescriptions per patient for other opioids (e.g. morphine, fentanyl and hydromorphone) commonly used to treat chronic cancer pain increased, argues against a blanket chilling effect of HB1. Similar results are noted for the benzodiazepines more commonly associated with abuse and diversion (alprazolam and diazepam) relative to clonazepam, which is often used for seizure control.

D. Prescriber Behavior

Changes in aggregate prescribing patterns were discussed in Project 1. This section explores individual prescribing patterns by using the dispensing data reported to KASPER to identify changes that may be related to HB1 by analyzing CS prescribing by volume of prescriptions issued, the prescribing patterns for opioids based on morphine milligram equivalents (MMEs) and finally, analyzing prescribing of potentially inappropriate drug combinations for patients (e.g. concurrent prescribing of an opioid, benzodiazepine and carisoprodol).

1. Prescribing by Volume of Prescriptions Issued

The vast majority of CS prescribing in Kentucky continues to be concentrated in a small number of prescribers. Figure 21a depicts the maximum number of CS prescriptions dispensed in each prescriber decile based on volume of prescriptions issued for the study period. In FY 2013, the top prescriber of CS in Kentucky had 72,141 prescriptions dispensed in his/her name. Figure 21b depicts the number of CS prescriptions dispensed by prescriber decile and fiscal year for the bottom nine deciles. This figure is presented without the upper decile to allow for visualization of changes in the bottom deciles that are not obvious due to the significant concentration of prescribing in the upper decile.

Figure 21a: Maximum Number of Prescriptions Dispensed for Top Prescribing Practitioners in Each Decile: KASPER, FY 2010 to FY 2013

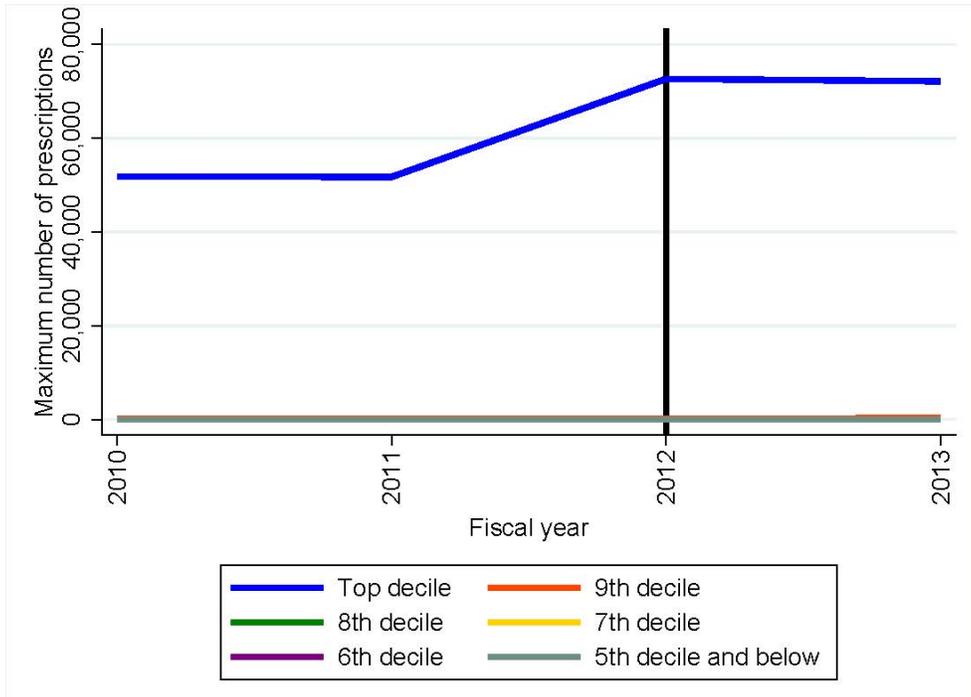
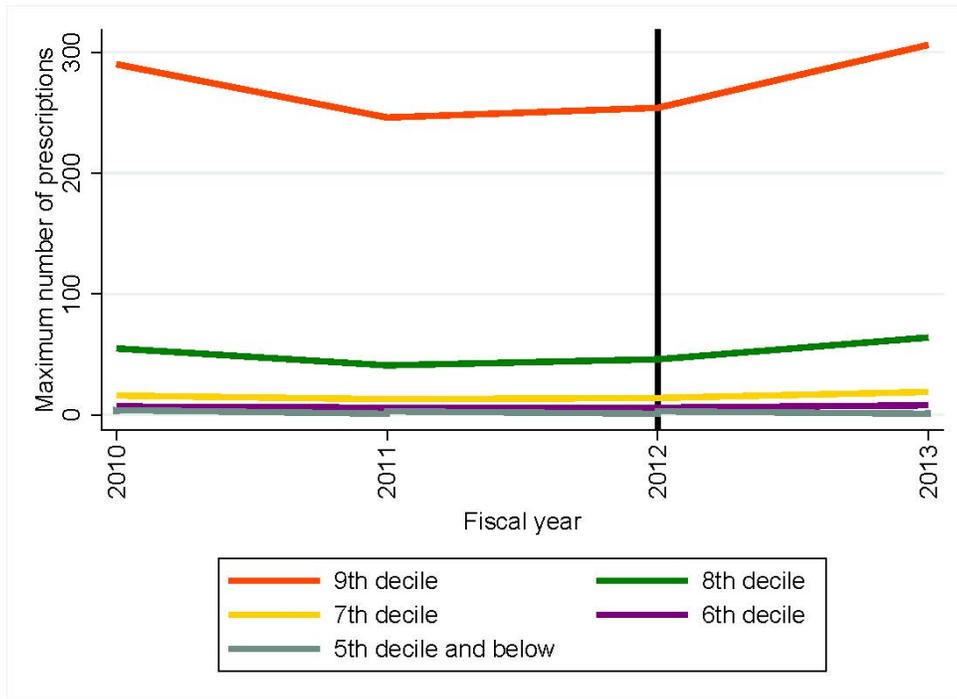


Figure 21b: Maximum Number of Prescriptions Dispensed for Top Prescribing Practitioners in Bottom Nine Deciles: KASPER, FY 2010 to FY 2013



Between FY 2012 and FY 2013, the number of CS prescribers in the top decile decreased by over 14% (from 5,840 to 5,566) and the number of prescriptions issued by the top decile of CS prescribers decreased by 8%. In 2013, 89.5% of all CS prescriptions dispensed were issued by the upper decile of prescribers, who issued a mean of 1,817 CS prescriptions compared to a mean of 24 CS prescriptions issued by prescribers in the bottom 9 deciles combined (Table 24). These results are also similar to what has been reported in other states such as Florida, which reported that in 2014, 82% of all CS prescriptions issued and reported to the Florida PDMP are issued by the top decile of prescribers.¹⁹

Table 24: Top Decile of Prescribers by Number of All Prescriptions Compared to Prescribers from Bottom Nine Deciles: KASPER, FY 2010 to FY 2013

		FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Number of prescribers in top decile	Number	5,840	10.43%	6,449	0.57%	6,486	-14.18%	5,566
	Number	10,396,347	3.77%	10,788,596	2.06%	11,011,242	-8.11%	10,118,294
Number of prescriptions dispensed for prescribers in top decile	Mean	1,780.20	-6.03%	1,672.91	1.48%	1,697.69	7.08%	1,817.88
	Median	857.50	-11.84%	756.00	0.53%	760.00	15.86%	880.50
	Maximum	51,795	-0.09%	51,747	40.40%	72,652	-0.07%	72,141
Number of prescriptions dispensed for prescribers in bottom nine deciles	Number	1,114,999	-9.99%	1,003,634	6.22%	1,066,039	10.88%	1,182,028
	Mean	21.20	-18.54%	17.27	5.62%	18.24	29.28%	23.58
	Median	3.00	0.00%	3.00	0.00%	3.00	0.00%	3.00
	Maximum	290	-15.17%	246	3.25%	254	20.47%	306

To determine if prescribing concentration varies based on drug class, and to see if HB1 preferentially impacted prescribing concentration for one drug class over others, prescriber deciles (by volume) were calculated for the select drug classes: opioids, benzodiazepines and stimulants. Figures 22a (all deciles) and 22b (bottom 9 deciles) show the maximum number of opioid prescriptions dispensed by prescriber decile by volume and fiscal year. In FY 2013, the top prescriber of opioids in Kentucky had

¹⁹ EFORCSE 2013-2014 Prescription Drug Monitoring Program Annual Report; available at <http://www.floridahealth.gov/statistics-and-data/e-forcse/news-reports/2014PDMPAnnualReportFinal.pdf>; last accessed 3-12-15.

34,349 opioid prescriptions dispensed in his/her name. The prescribing of opioids is highly concentrated in a small number of prescribers, although somewhat less concentrated than that observed for all CS.

Figure 22a: Maximum Number of Opioid Prescriptions Dispensed for Top Prescribing Practitioners in Each Decile: KASPER, FY 2010 to FY 2013

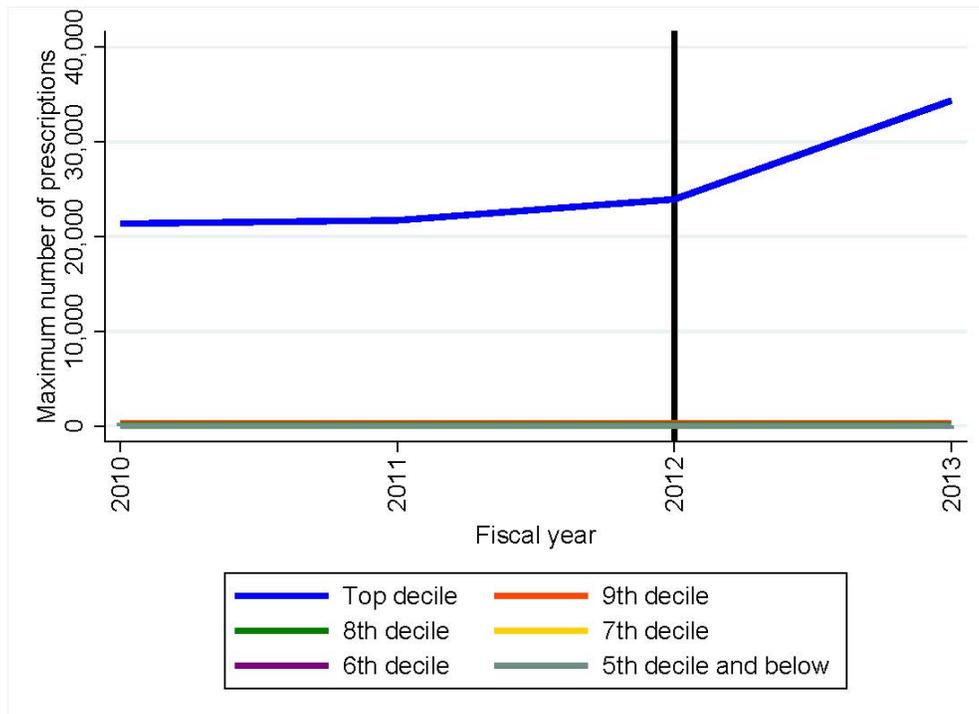
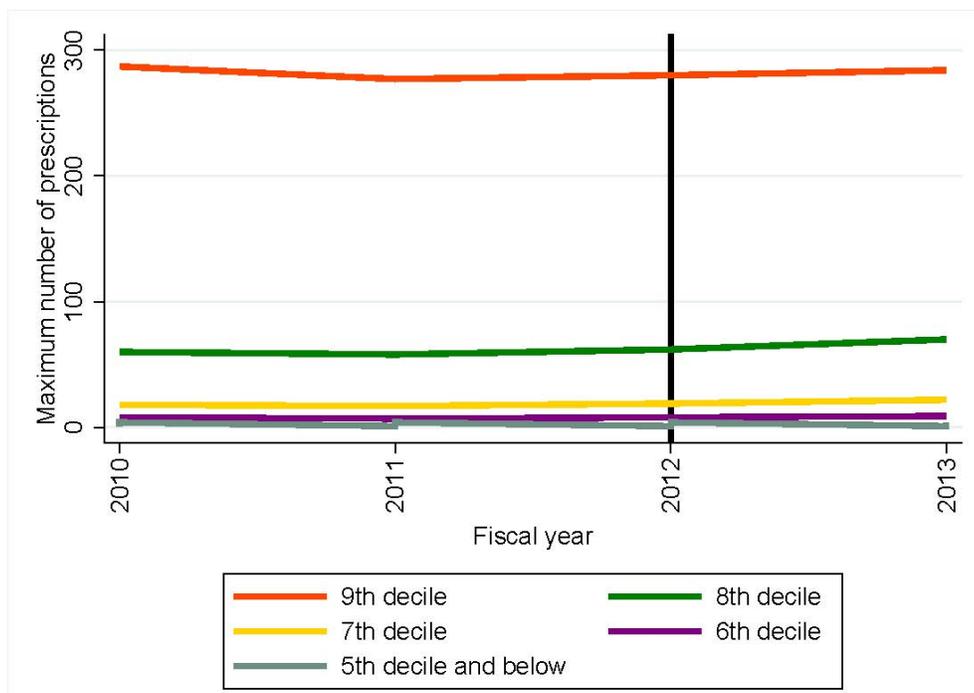


Figure 22b: Maximum Number of Opioid Prescriptions Dispensed for Top Prescribing Practitioners in Bottom Nine Deciles: KASPER, FY 2010 to FY 2013



Between FY 2012 and FY 2013, the number of opioid prescribers in the top decile decreased by over 9% (from 4,467 to 4,048) and the number of opioid prescriptions issued by the top decile of prescribers decreased by 10% (Table 25). In FY 2013, 85% of all opioid prescriptions dispensed were written by the top decile of prescribers, who issued a mean of 1,274 opioid prescriptions compared to a mean of 24 opioid prescriptions issued by prescribers in bottom 9 deciles combined (Table 25). Prior to HB1 in FY 2010 through FY 2012, the top deciles of prescribers were issuing 86-87% of all opioid prescriptions. Some of the changes observed in the upper decile of prescribers could be a result of the closures of rogue pain clinics that occurred as a result HB1, although this hypothesis cannot be confirmed with the data available for this study.

Table 25: Top Decile of Prescribers by Number of Opioid Prescriptions Compared to Prescribers from Bottom Nine Deciles: KASPER, FY 2010 to FY13

		FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Number of prescribers in top decile	Number	4,377	2.33%	4,479	-0.27%	4,467	-9.38%	4,048
	Mean	1,257.72	0.12%	1,259.25	1.88%	1,282.95	-0.67%	1,274.32
Number of prescriptions dispensed for prescribers in top decile	Median	710.00	-2.11%	695.00	-1.01%	688.00	-3.27%	665.50
	Maximum	21,366	1.66%	21,721	10.19%	23,935	43.51%	34,349
	Number	883,806	-1.92%	866,804	4.66%	907,195	-1.75%	891,321
Number of prescriptions dispensed for prescribers in bottom nine deciles	Mean	22.38	-4.11%	21.46	4.85%	22.50	8.58%	24.43
	Median	3.00	0.00%	3.00	0.00%	3.00	0.00%	3.00
	Maximum	287	-3.48%	277	1.08%	280	1.43%	284

Figures 23a (all deciles) and 23b (bottom 9 deciles) depict the maximum number of benzodiazepine prescriptions dispensed by prescriber decile (by volume) and fiscal year. Similar to that observed for all CS, the prescribing of benzodiazepines is highly concentrated in a small number of prescribers.

Figure 23a: Maximum Number of Benzodiazepine Prescriptions Dispensed for Top Prescribing Practitioners in Each Decile: KASPER, FY 2010 to FY 2013

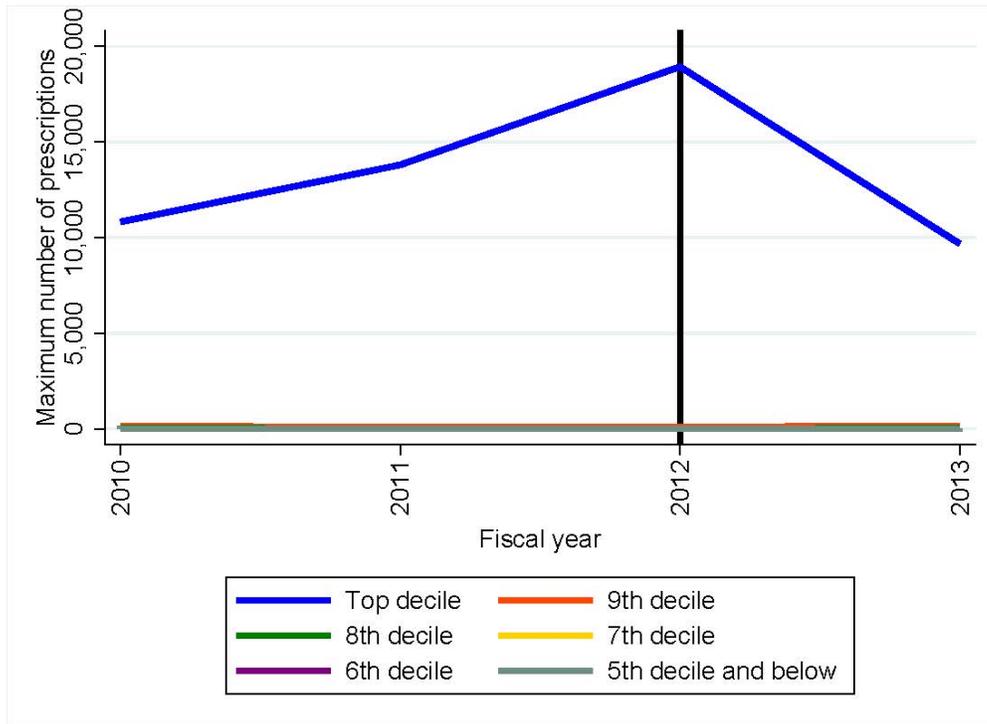
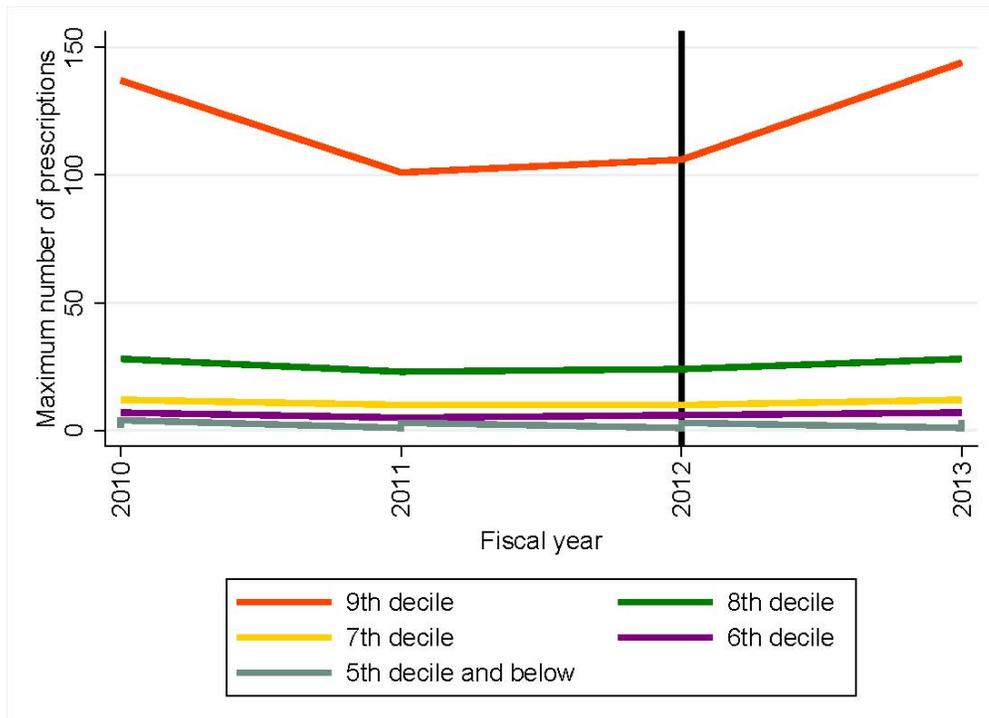


Figure 23b: Maximum Number of Benzodiazepine Prescriptions Dispensed for Top Prescribing Practitioners in Bottom Nine Deciles: KASPER, FY 2010 to FY 2013



In FY 2013, the top prescriber of benzodiazepines had 9,681 benzodiazepine prescriptions issued in his/her name, down almost 50% from FY 2012 when the top prescriber of benzodiazepines had 18,932 benzodiazepine prescriptions issued in his/her name. Between FY 2012 and FY 2013, the number of benzodiazepine prescribers in the top decile decreased by almost 15% (from 3,087 to 2,627) and the number of benzodiazepine prescriptions issued by the top decile of prescribers decreased by 9% (Table 26). In FY 2013, 89% of all benzodiazepine prescriptions dispensed were written by the top decile of prescribers, who issued a mean of 894 benzodiazepine prescriptions compared to a mean of 12 benzodiazepine prescriptions issued by prescribers in the bottom 9 deciles combined. As hypothesized above for opioids, the change in the number of prescriptions for benzodiazepines issued by the top prescriber might be the result of the closure of a rogue pain clinic, or disciplinary action and loss of license of the top prescriber in FY 2012.

Table 26: Top Decile of Prescribers by Number of Benzodiazepine Prescriptions Compared to Prescribers from Bottom Nine Deciles: KASPER, FY 2010 to FY 2013

		FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Number of prescribers in top decile	Number	2,701	13.37%	3,062	0.82%	3,087	-14.90%	2,627
	Mean	2,444,785	3.78%	2,537,153	1.79%	2,582,550	-9.03%	2,349,454
Number of prescriptions dispensed for prescribers in top decile	Mean	905.14	-8.46%	828.59	0.97%	836.59	6.90%	894.35
	Median	547.00	-15.72%	461.00	1.95%	470.00	15.53%	543.00
	Maximum	10,822	27.55%	13,804	37.15%	18,932	-48.86%	9,681
Number of prescriptions dispensed for prescribers in bottom nine deciles	Number	275,152	-8.73%	251,122	4.64%	262,772	5.85%	278,146
	Mean	11.3	-19.65%	9.08	3.96%	9.44	24.15%	11.72
	Median	3.00	0.00%	3.00	0.00%	3.00	0.00%	3.00
	Maximum	137	-26.28%	101	4.95%	106	35.85%	144

When stimulant prescriptions are separated from other CS prescriptions, prescribing concentrations are still evident, but appear somewhat more distributed among lower deciles. Figures 24a (all deciles) and 24b (bottom 9 deciles) show the maximum number of stimulant prescriptions dispensed by prescriber decile (by volume) and fiscal year. In FY 2013, the top prescriber of stimulants in Kentucky had 71,714 stimulant prescriptions dispensed in his/her name.

Figure 24a: Maximum Number of Stimulant Prescriptions Dispensed for Top Prescribing Practitioners in Each Decile: KASPER, FY 2010 to FY 2013

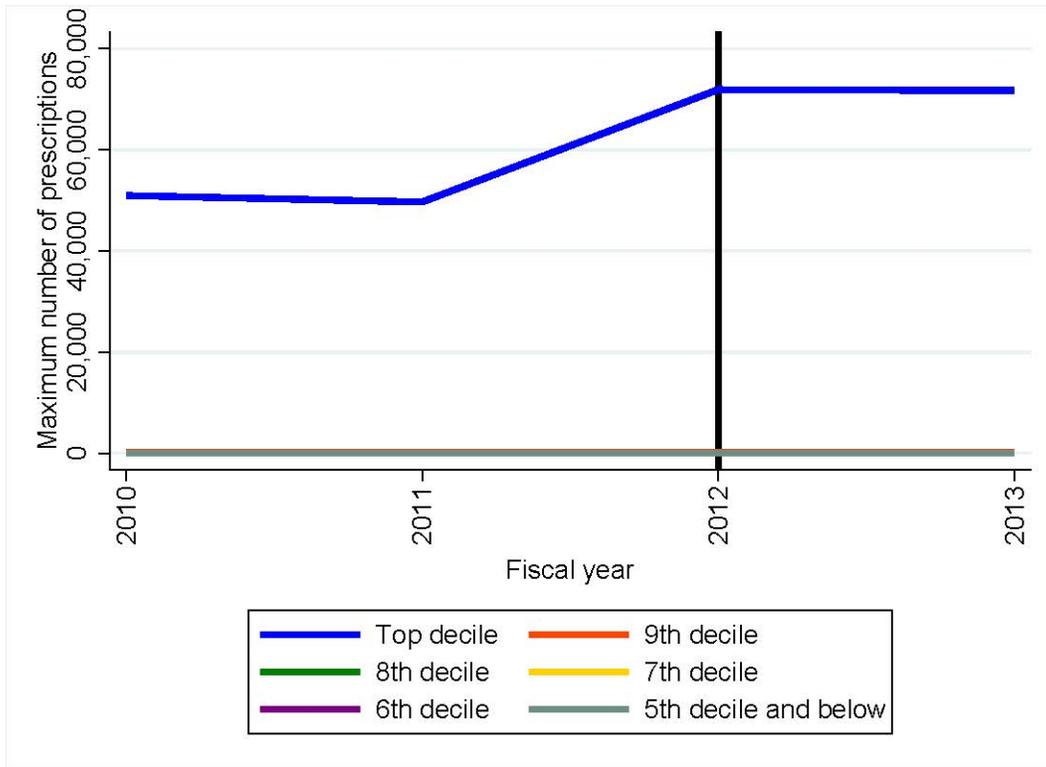
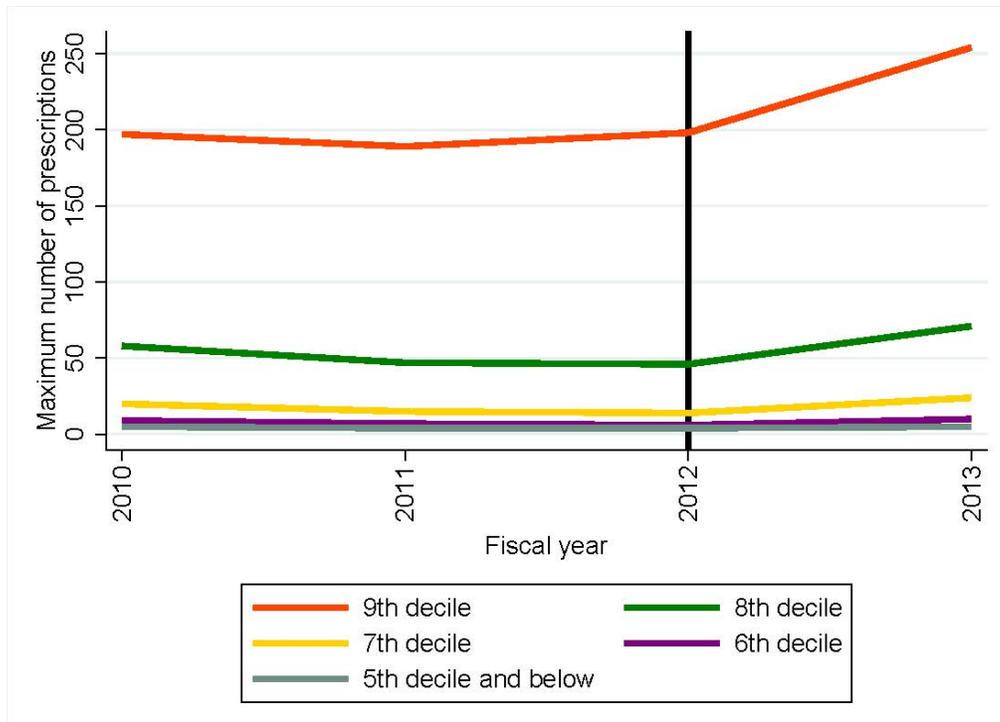


Figure 24b: Maximum Number of Stimulant Prescriptions Dispensed for Top Prescribing Practitioners in Bottom Nine Deciles: KASPER, FY 2010 to FY 2013



Between FY 2012 and FY 2013, the number of stimulant prescribers in the top decile decreased by almost 15% (from 1,377 to 1,172) while the number of stimulant prescriptions issued by the top decile of prescribers increased by over 5%. In FY 2013, 80% of all stimulant prescriptions dispensed were written by the top decile of prescribers, who issued a mean of 860 stimulant prescriptions compared to a mean of 24 stimulant prescriptions issued by prescribers in bottom 9 deciles combined (Table 27). Prior to HB1 in FY 2012, 82% of all stimulant prescriptions were issued by the top decile of prescribers.

Table 27: Top Decile of Prescribers by Number of Stimulant Prescriptions Compared to Prescribers from Bottom Nine Deciles: KASPER, FY 2010 to FY 2013

		FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Number of prescribers in top decile	Number	1,164	12.71%	1,312	4.95%	1,377	-14.89%	1,172
	Number	804,960	11.76%	899,660	6.25%	955,884	5.45%	1,008,015
Number of prescriptions dispensed for prescribers in top decile	Mean	691.55	-0.84%	685.72	1.23%	694.18	23.90%	860.08
	Median	413.00	-3.03%	400.50	0.62%	403.00	24.32%	501.00
	Maximum	50,954	-2.49%	49,686	44.72%	71,906	-0.27%	71,714
Number of prescriptions dispensed for prescribers in bottom nine deciles	Number	204,119	-2.84%	198,321	5.68%	209,592	21.46%	254,561
	Mean	19.70	-14.92%	16.76	0.78%	16.89	44.46%	24.40
	Median	4.00	-25.00%	3.00	0.00%	3.00	33.33%	4.00
	Maximum	197	-4.06%	189	4.76%	198	28.28%	254

Taken together, these results suggest that prescribing of all CS, as well as the prescribing of opioids, benzodiazepines and stimulants is highly concentrated in a relatively few number of prescribers. In FY 2013, the top decile of prescribers of benzodiazepines issued 89% of all benzodiazepine prescriptions and the top decile of prescribers of opioids issued 85% of all opioid prescriptions. Stimulant prescribing was slightly less concentrated in the upper decile, with 80% of all stimulant prescriptions attributed to prescribers in this decile.

To further assess the concentration of prescribing, the top 10 individual prescribers for each drug class were analyzed and the results are summarized in Table 28. In FY 2010, 272,449 CS prescriptions or 2.4% of all CS prescriptions dispensed were attributed to 10 individual prescribers. By FY 2013, the top 10 individual prescribers issued 311,626 CS prescriptions or 2.8% of all CS prescriptions dispensed. Similarly, a 1% increase (from 2.7% to 3.7%) in the number of opioid prescriptions attributed to the top 10 individual opioid prescribers is observed over the study period. Significant concentration is observed for oxycodone in the top 10 individual prescribers, who prescribed 6.2% of all oxycodone dispensed in FY 2010 compared to 8.9% of all oxycodone dispensed in FY 2013, and to a lesser extent, hydrocodone, for which prescribing attributed to the top 10 individual prescribers increased from 2.8% in FY 2010 to 3.4% in FY 2013. In contrast, benzodiazepine prescribing attributed to the top 10 individual prescribers of this drug class decreased from 3.2% in FY 2010 to 2.8% in FY 2013. The prescribing of stimulants follows similar trend as for opioids and all CS, with an increase in stimulant prescriptions attributed to the top 10 prescribers from 10% to 10.9% noted over the study period. Thus, although prescribing of stimulant class is less concentrated in the upper decile relative to opioids and benzodiazepines, as a class prescribing is more concentrated within the top 10 individual prescribers compared to the other drug classes.

Table 28: Number and Percent of Prescriptions Dispensed which Were Issued by Top Ten Prescribers: KASPER, FY 2010 – FY 2013

Drug Class		FY 2010	FY 2011	FY 2012	FY 2013
All prescriptions	Percent	2.37%	2.39%	2.49%	2.76%
	Number	272,449	281,721	301,046	311,626
Opioids	Percent	2.71%	2.77%	2.88%	3.72%
	Number	173,092	180,267	190,828	224,852
Hydrocodone	Percent	2.85%	2.64%	2.67%	3.38%
	Number	101,438	97,058	99,740	110,020
Oxycodone	Percent	6.22%	6.54%	8.04%	8.93%
	Number	56,540	66,999	88,232	86,426
Benzodiazepines	Percent	3.16%	3.38%	3.35%	2.79%
	Number	85,925	94,160	95,312	73,308
Stimulants	Percent	9.95%	10.38%	10.79%	10.90%
	Number	100,722	113,977	125,796	137,998

The results highlight the high volume of CS prescriptions written by the top prescribers. Using stimulants as an example, the top prescriber of stimulants in 2013 issued 71,714

stimulant prescriptions. Assuming the prescriber works 300 days per year (6 days per week for 50 weeks) for 8 hours a day, he or she would need to write 30 stimulant prescriptions per hour to issue 71,714 stimulant prescriptions in a year. The top prescriber of opioids in 2013 issued 34,349, and would need to write 14 opioid prescriptions per hour to issue this number over the course of a year. Since passage of HB1 and formation of the KASPER Advisory Council, there have been consistent efforts to identify and investigate top prescribers for inappropriate prescribing.

2. High Dose Oxycodone Prescribing

Multiple studies have documented the risk of unintentional drug overdose associated with high doses of opioids.²⁰ Because individual opioids vary in potency, conversion to an equivalent dose of morphine (MME) is often used to standardize and assess risk of opioid overdose. Depending upon the study, opioid doses equivalent to 80 or 100 MMEs have been associated with 6 – 11 fold increases in unintentional overdose depending upon the chronic conditions of the patients studied.²¹ The state of Washington has issued guidelines on opioid dosing for chronic non-cancer pain that recommend practitioners prescribe no more than an average daily morphine equivalent dose of 120mg without consultation from a pain management specialist.²²

To evaluate the impact of HB1 on high dose opioid prescribing, an MME conversion tool developed at the CDC was utilized to calculate MME for each opioid prescription in the KASPER dataset (see Appendix X). Based on evidence from Project 1 that suggested HB1 had the greatest impact on decreasing prescriptions for oxycodone, and given the fact that oxycodone has long been associated with the opioid abuse crisis in Kentucky, we chose to specifically evaluate the impact of HB1 on high dose oxycodone prescribing.

Figure 25 presents the number of patients receiving oxycodone therapy and the mean daily MME dose for all patients receiving oxycodone prescriptions by quarter across the study period. The number of patients receiving oxycodone prescriptions by quarter decreased immediately in the post-HB1 period, from a high of 28,644 patients to a low of 24,675 patients in 1st quarter of 2013. The mean MME per day ranged from a high of 118 in the 3rd quarter of 2010 to a low of 105 in 2nd quarter of 2013. It is interesting to

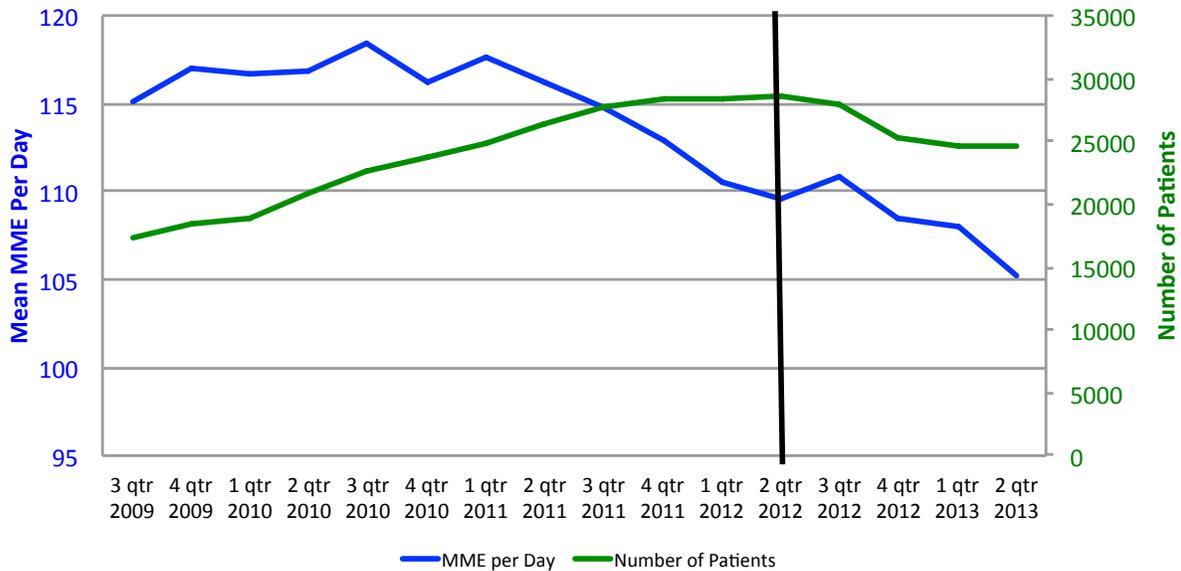
²⁰ CDC Grand Rounds: Prescription Drug Overdoses – A U.S. Epidemic. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm>; last accessed 3-15-15.

²¹ Bohnert AS, Valenstein M, Bair MJ, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. JAMA 2011;305:1315–21.

²² Washington Interagency guideline on opioid dosing for chronic non-cancer pain: an educational aid to improve care and safety with opioid therapy. Accessed at <http://www.guideline.gov/content.aspx?id=23792#Section424>; last accessed 3-17-15.

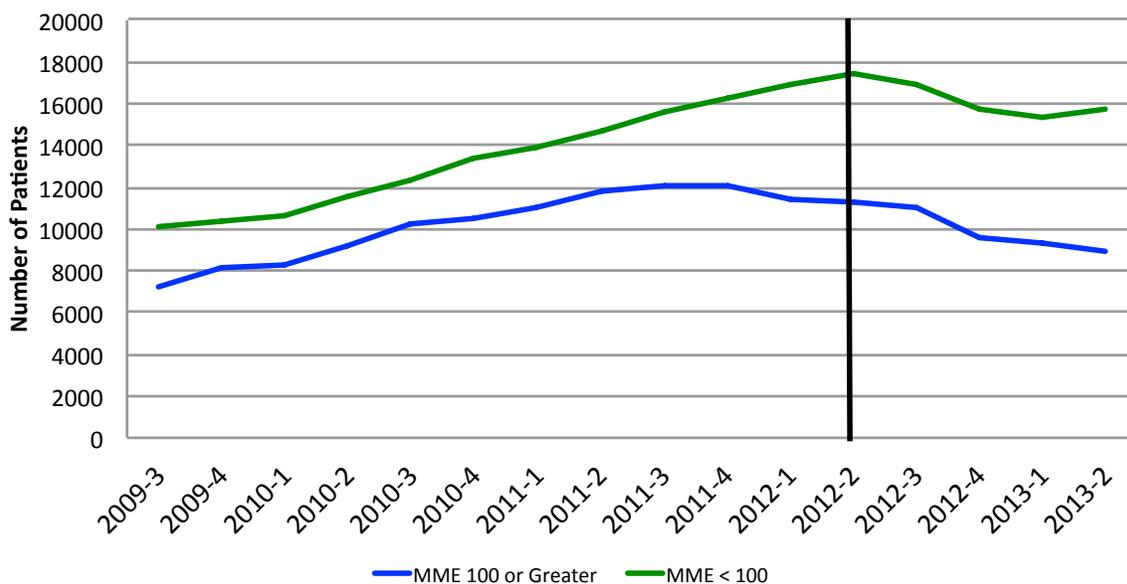
note that the downward trend in mean MME per day of oxycodone prescriptions began well before implementation of HB1 in July 2012.

Figure 25: Number of Patients and Mean Daily MME for Patients Receiving Oxycodone Prescriptions by Quarter, KASPER, FY10 - FY13



The number of patients receiving greater than 100 MME of oxycodone per day is depicted in Figure 26. A downward trend in the number of patients receiving greater than 100 MME per day is noted in the first quarter of 2012, prior to implementation of HB1 and is sustained throughout the remainder of the study period.

Figure 26: Number of Patients Receiving Oxycodone Prescriptions with Mean Daily MME Above and Below 100 Units by Quarter, KASPER, FY10 - FY13



3. Buprenorphine/Naloxone Prescribing

As a result of the Drug Addiction Treatment Act of 2000 (DATA 2000),²³ which allowed qualified physicians to apply for a waiver to dispense or prescribe specifically-approved narcotic medications, including buprenorphine/naloxone, for the treatment of opioid addiction in outpatient settings, office-based medication assisted treatment (MAT) has become a mainstay in the treatment of opioid addiction.²⁴ Physicians applying for a waiver under DATA 2000, must meet specific conditions and attest that they will not have more than 30 patients on MAT at any one time unless they reapply demonstrating need and intent to treat up to 100 patients. As of March 17, 2015, 23 treatment programs and 395 physicians were listed on SAMHSA's buprenorphine physician and treatment locator for Kentucky.²⁵ It should be noted that listing on the treatment locator is voluntary and thus not all physicians who have applied for and received a waiver under DATA (DW30 or DW100) may be listed on the physician locator. In 2013, data from the DEA registrant file was linked to the KASPER dataset as previously described (Appendix VII) which indicated that a total of 1,219 physicians in the KASPER dataset were registered as DW30 practitioners and 1,239 were registered as DW100 practitioners, with the majority of these being from out of state as only 217 physicians were registered as DW30 practitioners and 237 were registered as DW100 practitioners in Kentucky.

In addition to MAT, buprenorphine/naloxone can be prescribed off-label for pain, although little evidence exists as to the effectiveness of buprenorphine/naloxone over buprenorphine alone, of which two products (transdermal and injectable) are indicated by the FDA for treatment of pain.²⁶ To further assess prescribing patterns for buprenorphine/naloxone, which aggregate data in Project 1 (Table 3) showed significant increases each year of the study period, the number of unique buprenorphine/naloxone prescribers and the mean number of patients for whom they prescribe as well as the mean number of patients seen per prescriber were calculated and are presented in Figure 27. Significant changes in the prescribing of buprenorphine/naloxone have been observed throughout the study period.

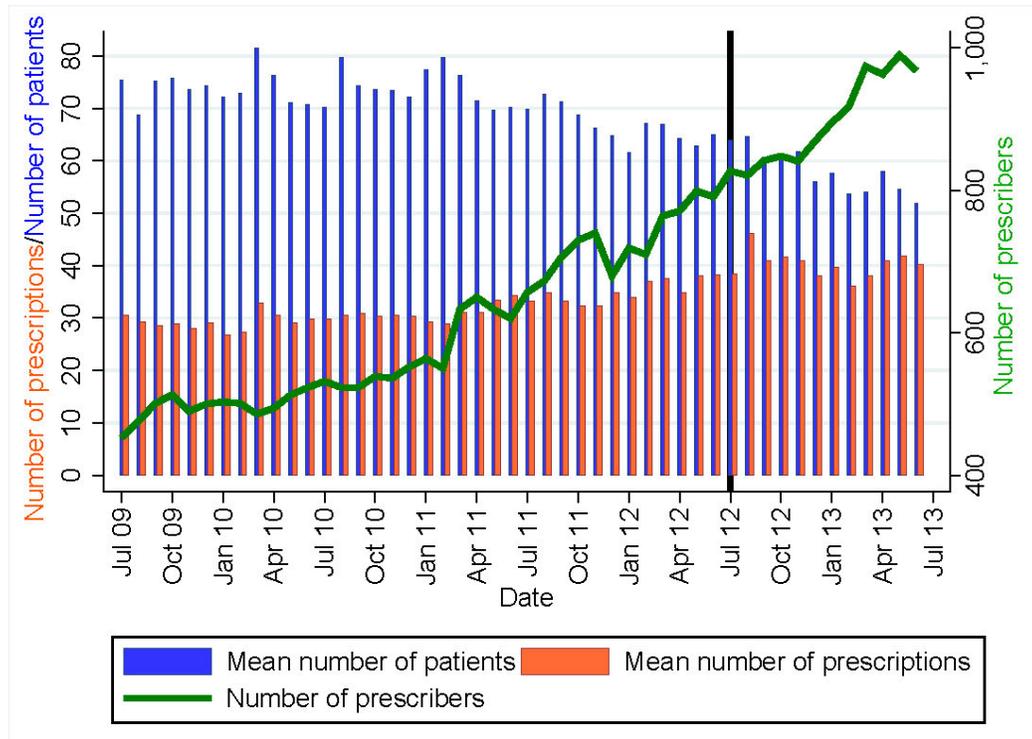
²³ SAMHSA. Drug Addiction Treatment Act of 2000. Available at <http://www.buprenorphine.samhsa.gov/fulllaw.htm>; last accessed 3-17-15.

²⁴ Medication-Assisted Therapies – Tackling the Opioid-Overdose Epidemic. N Engl J Med 2014; 370:2063-2066; available at <http://www.nejm.org/doi/full/10.1056/NEJMp1402780>; last accessed 3-14-15.

²⁵ SAMSHA Buprenorphine Physician and Treatment Locator. Available at http://buprenorphine.samhsa.gov/pls/bwns_locator/provider_search.process_query?alternative=CHOICEG&one_state=KY#physicians; last accessed 3-17-15.

²⁶ Buprenorphine with Naloxone from Chronic Pain, Ask the Expert: June 2014. Available at <http://www.practicalpainmanagement.com/treatments/pharmacological/opioids/buprenorphine-naloxone-chronic-pain>; accessed 3-14-15.

Figure 27: Kentucky Buprenorphine/Naloxone Prescribing Patterns: KASPER, KY 2010 to FY 2013



The number of buprenorphine/naloxone prescribers increased at a fairly steady rate throughout the study period. A slight increase in the mean number of buprenorphine/naloxone prescriptions dispensed per prescriber across the study period is evident. In contrast, the trend over the study period is for a decrease in the mean number of patients for whom prescribers issued buprenorphine/naloxone prescriptions. Thus, these data suggest that the significant increase in the number of buprenorphine/naloxone prescriptions observed between FY 2011 and FY 2012, and FY 2012 and FY 2013 (Project 1, Table 3 and Project 3, Table 21b) is largely driven by the significant increase in the number of unique buprenorphine/naloxone prescribers.

It would be interesting to determine what percent of the growth in prescribing of buprenorphine/naloxone is attributed to off-label use for pain vs. MAT. However, multiple limitations within the dataset preclude an accurate estimate. For example, prescribers who are registered with the DEA to prescribe CS, and have applied for and received a waiver to prescribe buprenorphine/naloxone under a DW30 or DW100 license, now have two similar numbers, a DEA number and a very similar DATA waiver number. The difficulty in attributing prescriptions correctly to these different numbers may contribute to data reporting errors. It is interesting to note that results from Project 2 suggest that prescribers are not referring patients to substance abuse treatment more

frequently since HB1, and as such, the increases in MAT observed following HB1 might be a result of individual patients recognizing need for and seeking MAT on their own.

Concern has been expressed regarding the potential abuse of buprenorphine/naloxone in Kentucky,²⁷ which has resulted in promulgation of professional standards for prescribing and dispensing of buprenorphine and buprenorphine/naloxone.²⁸ The question remains as to whether the rise in prescribing of buprenorphine/naloxone in Kentucky is reflective of an increase in the appropriate prescribing of MAT or if MAT is being used as a new means of doctor shopping to obtain buprenorphine for misuse, abuse and/or diversion.

4. Prescribing of Potentially Inappropriate Drug Combinations

To determine if HB1 impacted prescribing of medication combinations that are potentially inappropriate, the concurrent dispensing of an opioid (hydrocodone or oxycodone), alprazolam and carisoprodol (OAC) was evaluated over the study period. This combination, known as the ‘holy trinity’ on the street, has been associated with ‘pill mills’ and is often sought after by doctor shoppers.²⁹ Patients who received a prescription for all three medications within a one-month period were defined as having concurrent prescriptions for OAC. In FY 2010, 22,423 instances of concurrent therapy for OAC were evident, increasing in FY 2011 to 25,465.

Table 29: Total Patient/Months of Concurrent Prescriptions of an Opioid, Alprazolam and Carisoprodol (OAC): KASPER, FY 2010 to FY 2013

	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Number of patient/months	22,423	13.57%	25,465	-10.48%	22,795	-29.88%	15,983
Percent of all patient/months	0.32%		0.35%		0.31%		0.22%

Source: Cabinet for Health and Family Services, KASPER administrative dataset

²⁷ Laura Unger. Addiction Medicine Suboxone Now Being Abused. The Courier Journal. Available at <http://www.courier-journal.com/story/news/local/2014/07/03/addiction-medicine-suboxone-now-abused/12153725/>; last accessed 3-23-15.

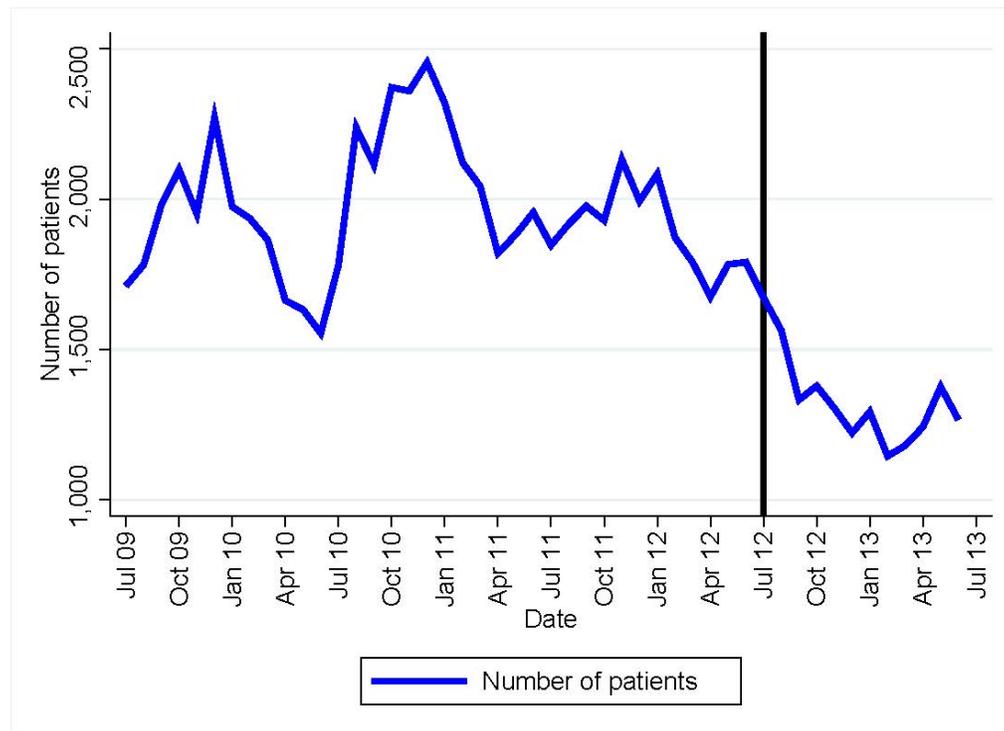
²⁸ Kentucky Administrative Regulations. 201 KAR 9:270: Professional standards for prescribing or dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone. Available at <http://www.lrc.ky.gov/kar/201/009/270reg.htm>; last accessed 3-23-15.

²⁹ Joseph T. Rannazzisi. Prescription Drug Diversion: Combating the Scourge. Statement before the Subcommittee on Commerce <http://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/03/01/12//03-01-12-dea-rannazzisi-testimony.pdf>; last accessed 3-14-15.

A 10.5% decrease in concurrent dispensing of this drug combination is noted between FY 2011 and FY 2012, while an impressive 30% decrease in concurrent OAC therapy is observed between FY 2012 and FY 2013 following implementation of HB1 (Table 29).

Figure 28 depicts the monthly trends over the study period for the number of instances concurrent prescriptions for OAC were dispensed. Although a downward trend is noted prior to HB1 implementation in 2012, a continued downward trend that is sustained for the remainder of the study period is observed following implementation of HB1.

Figure 28: Number of Patients Receiving Concurrent Prescriptions of an Opioid, Alprazolam and Carisoprodol (OAC) in a Month: KASPER, FY 2010 to FY 2013



These results suggest that HB1 had a significant impact on inappropriate prescribing, either through the strengthened pain clinic regulations that resulted in closure of several pain clinics immediately following HB1 implementation or through changes in prescribing behavior of individual prescribers who make different treatment decisions as a result of querying the KASPER system under the HB1 mandate.

Taken together, these results suggest that the prescribing of CS in Kentucky remains highly concentrated, with between 80 and 90% of the CS prescriptions dispensed (based on drug class) issued by the top decile of prescribers. HB1 had a significant impact on prescribing behavior as evidenced by decreases in high dose oxycodone prescribing and decreases in number of patients receiving concurrent therapy for the 'holy trinity.' Significant increases in prescribing of buprenorphine/naloxone is driven by a large increase in the number of buprenorphine/naloxone prescribers, although it is

unclear what percentage of this increase is for MAT and what is off-label use for treatment of pain.

E. Patient Behavior

One of the main behaviors legislators hoped to impact with the passage of HB1 was that of “doctor shopping.” The term, according to the CDC,³⁰ has traditionally referred to a patient obtaining controlled substances from multiple health care practitioners without the prescribers’ knowledge of the other prescriptions, often filled at multiple pharmacies. These “multiple provider episodes” (MPE) have been used as metrics to document effectiveness of PDMPs.³¹ The prevalence of MPEs or doctor shopping reported in the literature has ranged from as low as 0.2% in a general patient population to up to 8% depending on the population studied and the criterion used to define questionable activity.³² Thresholds for what meets the definition of doctor shopping vary, with many criterion used. In Kentucky, the CHFS has recently relied on a criterion of 4 plus 4: defined as a patient receiving multiple prescriptions from 4 or more different prescribers and filled at 4 or more different pharmacies within a specified time period. For the purposes of analyzing the impact of HB1 on doctor shopping behavior, data from the KASPER database were coded to identify the number of individuals who received multiple CS prescriptions from 4 unique prescribers and filled at 4 unique pharmacies within a three-month period (quarter).

Table 30 shows the number of patients meeting the 4 plus 4 criterion for doctor shopping in the KASPER database during the study period. The number of patients meeting the criterion decreased by over 50% between FY 2012 and FY 2013 following implementation of HB1. Additionally, of the patients meeting the criterion, there are significant but small (<5%) decreases in the mean number of total prescriptions dispensed per patient and the mean number of opioid prescriptions dispensed per patient. The fact that the total number of patients meeting the criterion is decreased by a significantly larger margin than the mean number of prescriptions per patient argues against a chilling effect of HB1, in that patients who may have legitimate reasons for seeing multiple providers (primary care and specialists, for example) are still receiving prescriptions from multiple providers in the post-HB1 period.

³⁰ CDC Home and Recreational Safety, Law: Doctor Shopping; available at http://www.cdc.gov/homeandrecreationalsafety/Poisoning/laws/dr_shopping.html; last accessed 3-4-15.

³¹ Prescription Drug Monitoring Programs: Assessment of the Evidence for Best Practices. Prescription Drug Monitoring Program Center of Excellence. Available at http://www.pewtrusts.org/~media/Assets/0001/PDMP_Update_1312013.pdf; last accessed 3-12-15.

³² PDMP Center of Excellence Study Analysis 01. Identifying probable doctor shopping and other questionable activity using prescription monitoring data: some preliminary findings. Available at http://www.pdmpexcellence.org/sites/all/pdfs/COE_rpt_dr_shopping_6.pdf; last accessed 3-17-15.

Table 30: Doctor Shopping, Patients having Prescriptions Prescribed by Four or More Prescribers and being Dispensed from Four or More Pharmacies in One Three-Month Period: KASPER, FY 2010 to FY 2013

		FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Number of patients in a quarter for one fiscal year meeting 4 plus 4 criterion	Per year	16,539	-7.50%	15,298	-5.51%	14,455	-51.83%	6,963
	Per quarter	4,135	-7.50%	3,825	-5.51%	3,614	-51.83%	1,741
Number of prescriptions dispensed to patients meeting 4 plus 4 criterion	Number	198,420	-10.00%	178,584	-5.57%	168,630	-53.11%	79,064
	Mean	12.00	-2.75%	11.67	0.00%	11.67	-2.74%	11.35
	Median	11.00	-9.09%	10.00	10.00%	11.00	-9.09%	10.00
Number of opioid prescriptions dispensed to patients meeting 4 plus 4 criterion	Number	139,348	-9.12%	126,639	-5.79%	119,303	-54.11%	54,743
	Mean	8.43	-1.78%	8.28	-0.36%	8.25	-4.73%	7.86
	Median	8.00	-12.50%	7.00	0.00%	7.00	0.00%	7.00

The number of individuals who met the 4 plus 4 criterion each quarter during the study period, and the number of prescriptions they received are displayed in Figure 29. A sharp decrease in both number of patients and number of prescriptions for patients meeting the 4 plus 4 criterion is noted immediately following implementation of HB1.

Figure 29: Doctor Shopping, Number of Patients and Prescriptions: Patients having Prescriptions Prescribed by Four or More Prescribers and being Dispensed from Four or More Pharmacies in One Three-Month Period (Quarter): KASPER, FY 2010 to FY 2013

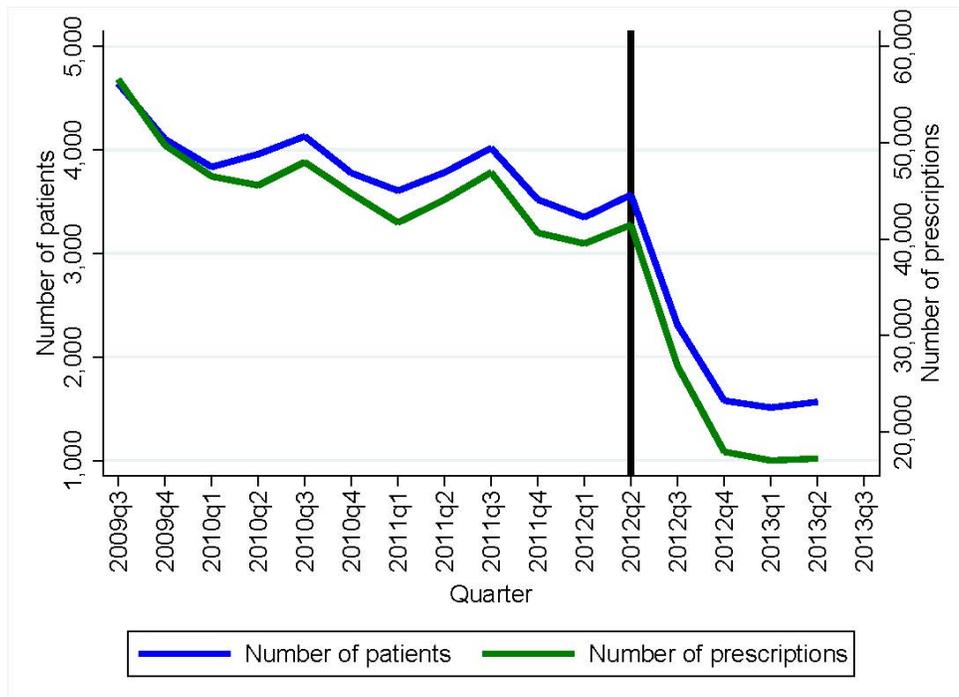
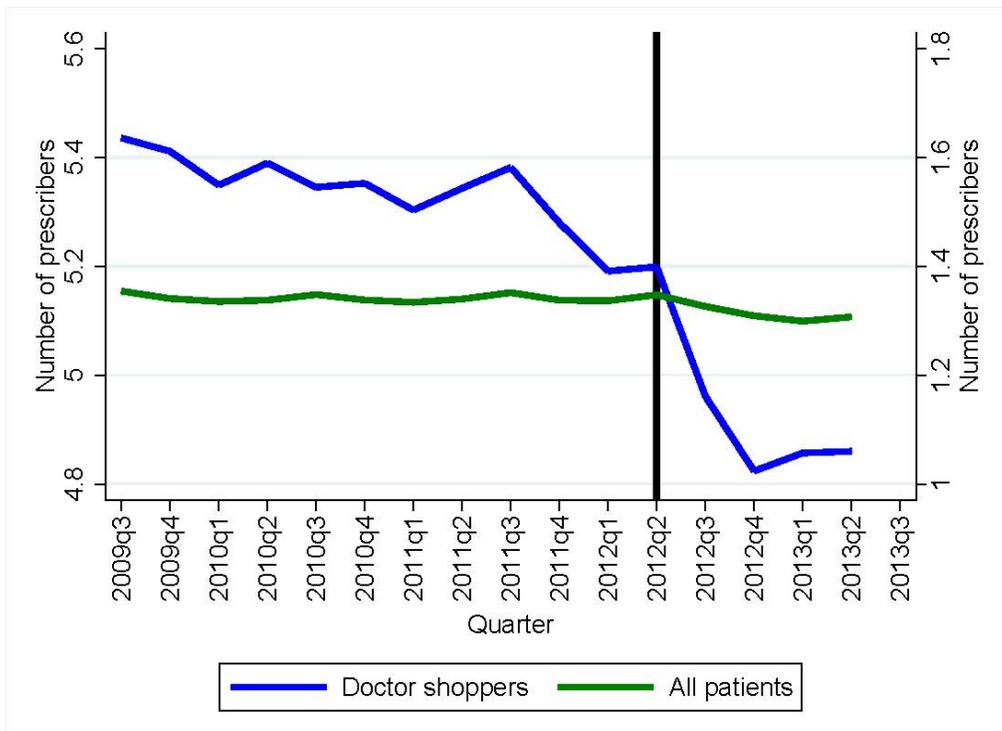


Figure 30 compares the mean number of prescribers and prescriptions dispensed to patients meeting the 4 plus 4 criterion compared to all other patients in the KASPER dataset. The mean number of prescribers used by patients meeting the doctor shopping criterion decreased from a high of 5.4 in 3rd quarter 2009, to a low of 4.8 in the post-HB1 period. For all other patients, the mean number or prescribers ranged from a high of 1.35 in 3rd quarter 2009 to a low of 1.3 in the post-HB1 period.

Figure 30: Mean Number of Prescribers for Patients Meeting the 4 Plus 4 Criterion Compared to All Patients: KASPER, QY 2010 to QY 2013



In 2011, the Government Accountability Office (GAO) issued a report to Congress relative to the instances of questionable access to prescription drugs in the Medicare Part D program.³³ In this study, the GAO analyzed Medicare Part D claims to identify potential doctor shoppers for 14 categories of frequently abused prescription drugs, including oxycodone and hydrocodone. In this study, the GAO found that 2.8% of all beneficiaries receiving oxycodone and 1.8% of all beneficiaries receiving hydrocodone were receiving them from 5 or more prescribers. A significant number of these beneficiaries received these two medications from 11-15 prescribers and some from 21 – 50 prescribers.

To compare the number of possible doctor-shopping patients in KASPER pre-post HB1 to that reported by the GAO, patients receiving prescriptions for hydrocodone or

³³ GAO-11-699. Medicare Part D: Instances of Questionable Access to Prescription Drugs. Available at www.gao.gov/products/GAO-11-699; last accessed 3-23-15.

oxycodone from 5 or more unique prescribers in one fiscal year for the study period were analyzed and the results are presented in Table 31.

Table 31: Doctor Shopping, Number of Patients Receiving Prescriptions from Five or More Unique Prescribers in One Fiscal Year: KASPER, FY 2010 to FY 2013

	FY 2010	Percent change (FY10-11)	FY 2011	Percent change (FY11-12)	FY 2012	Percent change (FY12-13)	FY 2013
Hydrocodone							
5-10 prescribers	19,002	-2.27%	18,571	1.25%	18,803	-34.86%	12,249
11-15 prescribers	654	-8.72%	597	-6.87%	556	-85.43%	81
16-20 prescribers	103	-10.68%	92	-20.65%	73	-87.67%	9
21-50 prescribers	58	-24.14%	44	-13.64%	38	-97.37%	1
51 + prescribers	2	-50.00%	1	-100.00%	0	0.00%	0
Oxycodone							
5-10 prescribers	3,879	24.85%	4,843	15.09%	5,574	-25.55%	4,150
11-15 prescribers	83	28.92%	107	20.56%	129	-64.34%	46
16-20 prescribers	7	57.14%	11	81.82%	20	-85.00%	3
21-50 prescribers	4	0.00%	4	50.00%	6	-100.00%	0
51 + prescribers	0	100.00%	1	-100.00%	0	0.00%	0

In FY 2012, almost 19,000 patients received prescriptions for hydrocodone from 5 – 10 unique prescribers and over 5000 patients received prescriptions for oxycodone from 5 – 10 unique prescribers. Following HB1, the number of patients receiving oxycodone prescriptions decreased by 25% for those seeing 5 – 10 prescribers and by 100% for those receiving prescriptions from 21-50 unique prescribers. Similar results are noted for suspected doctor shoppers of hydrocodone, with a 35% decrease post-HB1 in the number of patients receiving prescriptions from 5 – 10 prescribers and a 97% decrease in number of patients receiving prescriptions from 21 - 50 prescribers.

Taken together, these results suggest HB1 had an immediate and significant impact on doctor-shopping behavior as defined by the 4 plus 4 criterion and as defined by the metrics utilized in the GAO report. This supports qualitative evidence gleaned from the stakeholder interviews and surveys of KASPER registrants that HB1 impacted doctor-shopping behavior and that KASPER is an effective tool to reduce doctor shopping.

F. Outcomes

1. Substance Abuse Treatment Admissions

Admissions to treatment facilities for substance abuse in Kentucky and the surrounding states were identified using the Treatment Episode Data Set (TEDS) from the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency of the U.S. Department of Health and Human Services.³⁴ The Treatment Episode Data is an administrative data system providing descriptive information about the national flow of admissions to substance abuse treatment providers/facilities. The dataset is available to the public for retrieval and analysis and is a continuation of the former Client Data System (CDS) that was originally developed by the Alcohol, Drug Abuse, and Mental Health Services Administration. The dataset includes facilities that are licensed or certified by the state substance abuse agency to provide substance abuse treatment (or are administratively tracked for other reasons), and that are required by the states to provide TEDS client-level data. While comprising a significant proportion of all admissions to substance abuse treatment facilities, TEDS does not include all such admissions. The scope of admissions included in TEDS is affected by differences in state reporting practices, varying definitions of treatment admissions, availability of public funds, and public funding constraints. In 1997, TEDS was estimated to include 83% of TEDS-eligible admissions and 67% of all known admissions. It is important to note that each year only a fraction of those who report non-medical use of prescription opioids actually seek treatment.

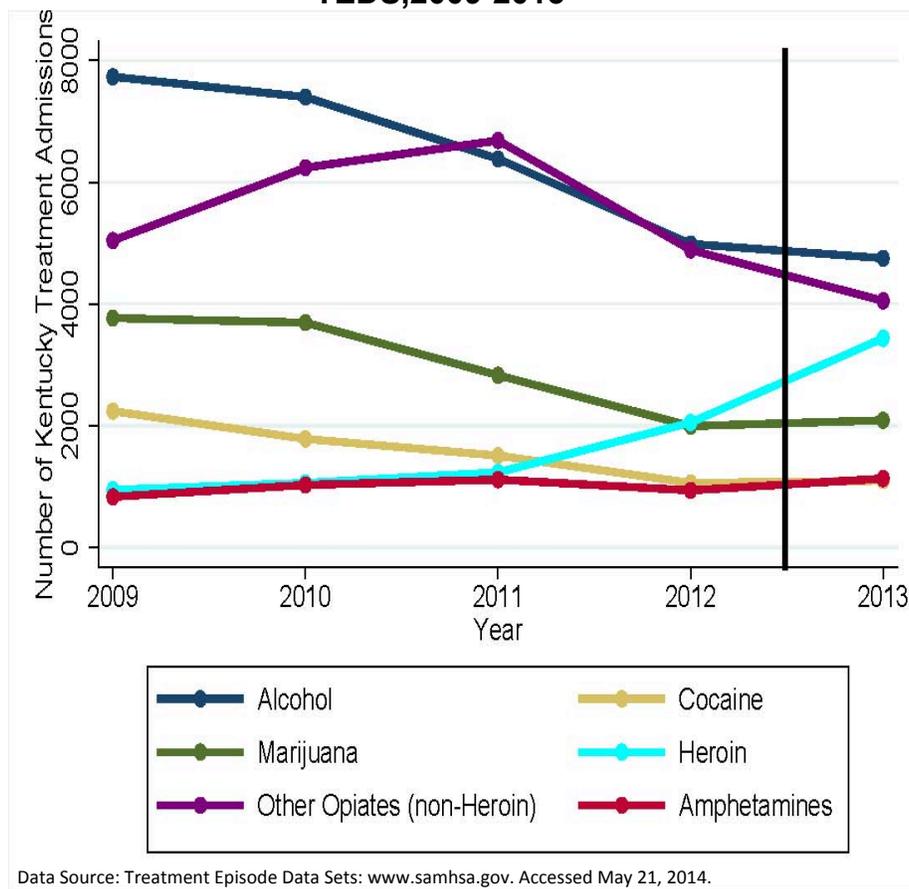
For this report, we analyzed TEDS data from 2009 to 2013 to assess admission rate for substance abuse for all substances reported, including prescription opioids, stimulants (amphetamines) and heroin. One could hypothesize that if KASPER were having an impact on reducing prescription CS abuse, more patients would seek treatment for substance abuse and thus admissions for substance abuse treatment would increase. Others have stated the opposite hypothesis and suggested that admission rates would decrease if PDMPs were effective.³⁵ Other variables that could contribute to increased rate of admissions include overall increase in the number of individuals with substance abuse, changes in the number of treatment beds and/or changes in reporting of substance abuse admissions from facilities to SAMSHA for inclusion in the TEDS database.

³⁴ Treatment Episodes Data Set, Substance Abuse and Mental Health Services Administration at <http://www.dasis.samhsa.gov/webt/NewMapv1.htm>; last accessed 5-21-14.

³⁵ Reiseman et al, Prescription Opioid Usage and Abuse Relationships: An Evaluation of State Prescription Drug Monitoring Program Efficacy, *Substance Abuse: Research* 2009; 3: 41 – 51.

Figure 32 depicts substance abuse treatment admissions by type of substance in Kentucky for calendar years 2009 to 2013. Admissions for opiates other than heroin (other opiates) increased between 2009 and 2011 and, in fact, have increased every year between 1997 and 2011.³⁶ Beginning in 2011, a decrease in the number of treatment admissions related to other opiates is observed. Also observed in 2011 is a sharp increase in the number of treatment admissions related to heroin, which continues throughout the remainder of the study period. This increase in heroin-related treatment admissions is noted well before implementation of HB1 in July 2012 as depicted by the black vertical line in Figure 32 below.

Figure 32: Kentucky Substance Abuse Treatment Admissions, TEDS, 2009-2013



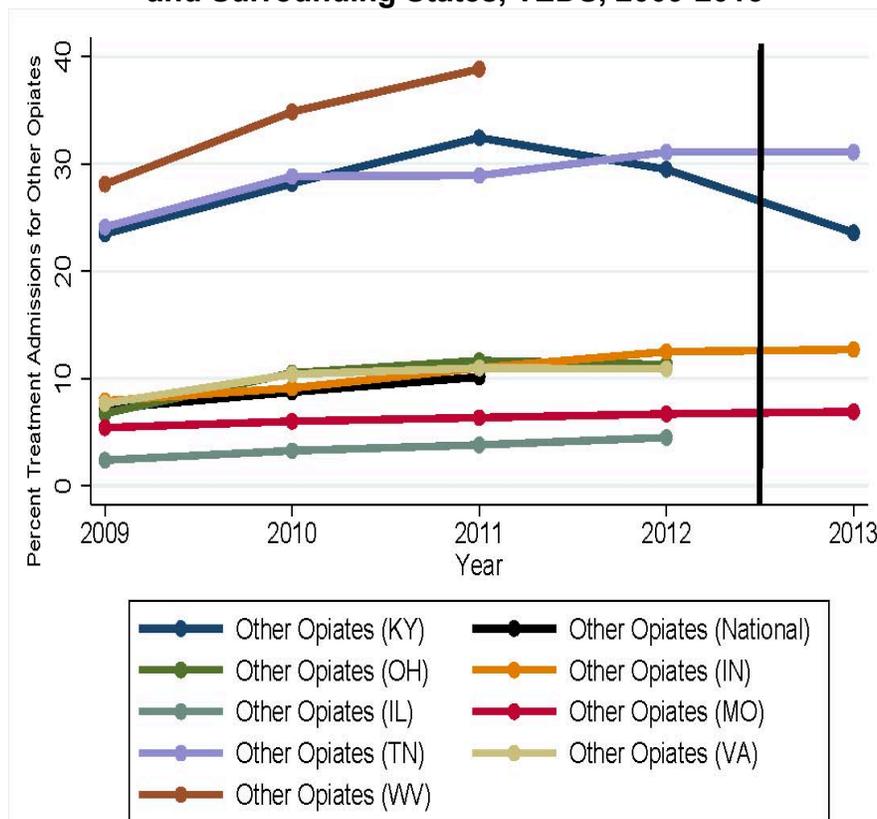
It is interesting to note that the increasing trend for heroin-related treatment admissions in Kentucky appears more temporally related to the reformulation of OxyContin® to the abuse deterrent formulation that occurred in late 2010. Prior to this time, the original formulation of OxyContin® was commonly abused through alternative routes of

³⁶ Independent Evaluation of the Impact and Effectiveness of the Kentucky All Schedule Prescription Electronic Reporting Program (KASPER). Available at <http://www.chfs.ky.gov/NR/rdonlyres/24493B2E-B1A1-4399-89AD-1625953BAD43/0/KASPEREvaluationFinalReport10152010.pdf>; last accessed 3-14-15.

administration including crushing and snorting or injecting. Following reformulation, the routes by which OxyContin® could be readily abused were limited, likely making it less attractive to opioid abusers than heroin. At the same time, evidence suggests that changes in the street price and availability of heroin may also have contributed to an increase in heroin abuse over prescription opioids.³⁷

To compare trends in ‘other opiate’ treatment admissions in Kentucky to surrounding states, other opiate treatment admissions, expressed as a percentage of all treatment admissions in Kentucky, Ohio, Illinois, Indiana, Missouri, Tennessee, Virginia and West Virginia are represented in Figure 33. Treatment admissions for other opiates across the nation are also compared. In addition to Kentucky, Ohio also shows a decrease in other opiate treatment admissions beginning in 2011. Other border states show a slow but steady increase in other opiate treatment admissions.

Figure 33: Substance Abuse Treatment Admissions for Other Opiates in Kentucky and Surrounding States, TEDS, 2009-2013



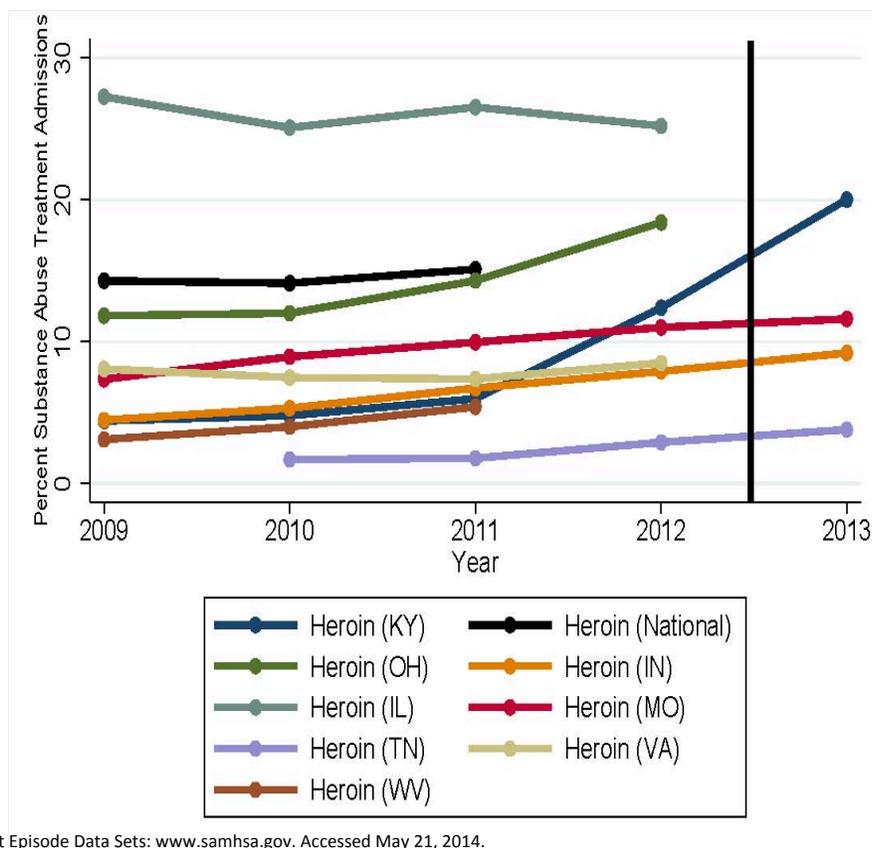
Data Source: Treatment Episode Data Sets: www.samhsa.gov. Accessed May 21, 2014.

To compare trends in heroin treatment admissions in Kentucky to surrounding states, heroin treatment admissions, expressed as a percentage of all treatment admissions in

³⁷Cicero, TJ and Surratt, HL. Effect of Abuse-Deterrent Formulation. N Engl J Med 2012; 367:187-189. Available at <http://www.nejm.org/doi/full/10.1056/NEJMc1204141>; last accessed 3-15-15

Kentucky, Ohio, Illinois, Indiana, Missouri, Tennessee, Virginia and West Virginia are represented in Figure 34. Treatment admissions for heroin across the nation as a whole are also compared. In addition to Kentucky, Ohio showed an increasing trend in heroin treatment admissions beginning in 2011. Other border states showed a slow but steady increase in heroin treatment admissions, while the national average remained relatively flat from 2009 to 2011.

Figure 34: Substance Abuse Treatment Admissions for Heroin in Kentucky and Surrounding States, TEDS, 2009-2013



Data Source: Treatment Episode Data Sets: www.samhsa.gov. Accessed May 21, 2014.

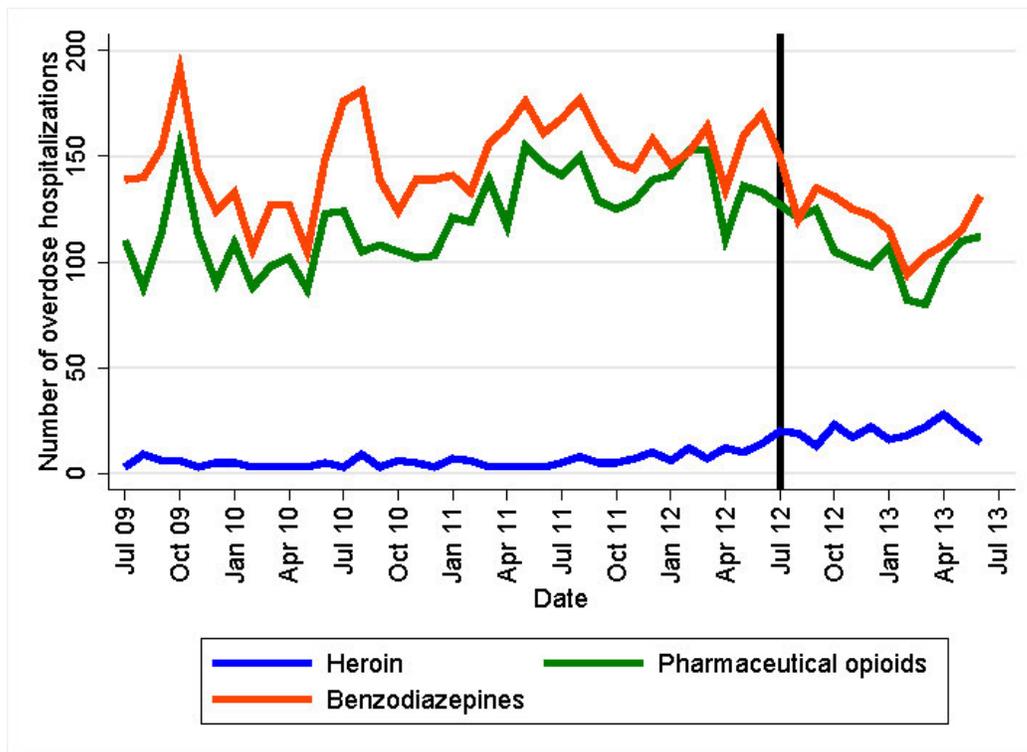
One possible explanation for decrease in substance abuse treatment admissions observed for other opiates is that patients in need of treatment are choosing office based MAT at sites that are not reported to TEDS. The significant increases in prescribing of buprenorphine/naloxone over the study period may support this hypothesis.

2. Morbidity from Drug Overdose

To assess morbidity from drug overdose during the study period, data from the Kentucky Office of Vital Statistics were obtained for the years 2009 to 2013. Figure 35 depicts hospital discharges for drug overdoses attributed to pharmaceutical opioids, benzodiazepines and heroin in Kentucky from 2009 to 2013. Hospital discharges

associated with pharmaceutical opioids and benzodiazepines were increasing between 2009 and 2012, when they began to slightly decrease. Discharges for these substances have continued to decline since 2012. Discharges associated with heroin began increasing in mid-2011 and have continued to increase throughout the remainder of the study period. Again, it is important to note that these changes in trends related to morbidity from drug overdoses due to pharmaceutical opioids, benzodiazepines and heroin began prior to implementation of HB1 in July 2012.

Figure 35: Hospital Discharges for Overdose in Kentucky, by Substance: FY 2010 to FY 2013



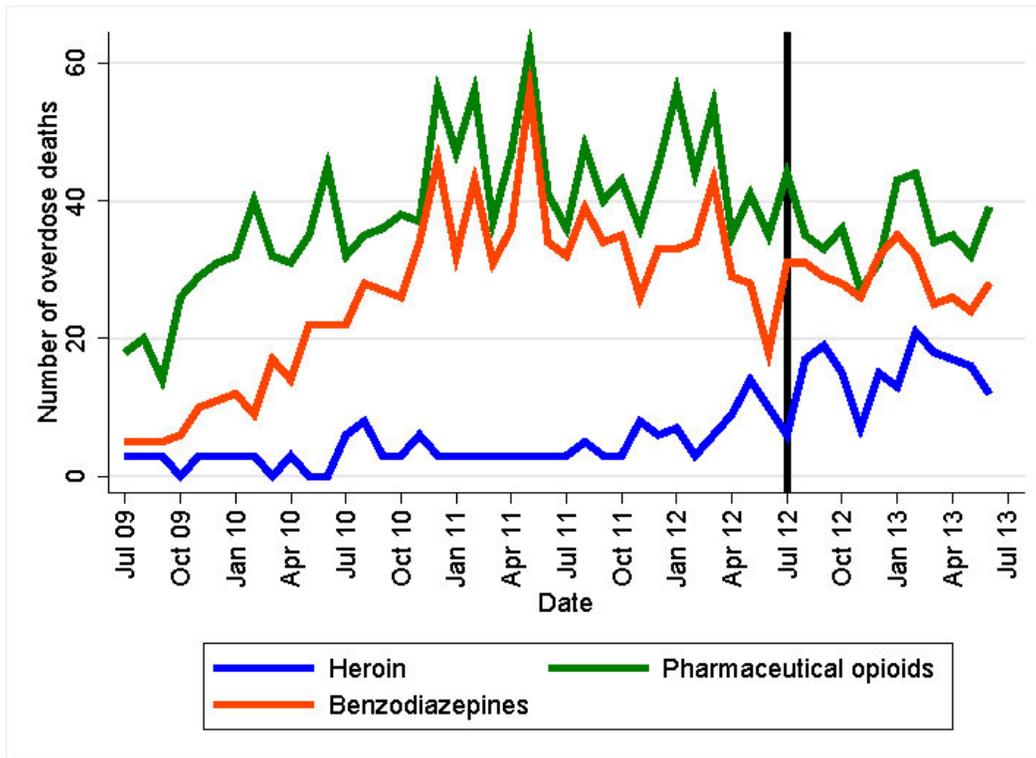
Source: Kentucky Office of Vital Statistics summarized by The Kentucky Injury Prevention and Research Center, 2014.

3. Mortality from Drug Overdose

To assess mortality from drug overdose during the study period, data from the Kentucky Office of Vital Statistics was obtained for the years 2009 to 2013. Figure 36 depicts overdose deaths attributed to pharmaceutical opioids, benzodiazepines and heroin in Kentucky for the years 2009 to 2013. Deaths associated with pharmaceutical opioids and benzodiazepines peaked in 2011 and began to slightly decrease. Overdose deaths associated with these two classes of drugs have continued to decline since 2011. Deaths associated with heroin began increasing in late 2010 and have continued to

increase throughout the remainder of the study period. Again, it is important to note that the trend shifts in overdose deaths from pharmaceutical opioids and benzodiazepines to heroin began prior to implementation of HB1 in July 2012.

Figure 36: Overdose Deaths in Kentucky, by Substance: FY 2010 to FY 2013



Source: Kentucky Office of Vital Statistics summarized by The Kentucky Injury Prevention and Research Center, 2014.

G. Project 3 Summary

Taken together, the results of Project 3 provide evidence that HB1 had significant impact on prescribing behavior, patient behavior and outcomes of substance misuse and abuse. Following implementation of HB1, the number of unique prescribers and unique patients in the KASPER dataset decreased, with the decrease in prescribers attributed to a decrease in out-of-state prescribers. Evidence from this evaluation showed that the number of Kentucky prescribers, including prescribers in both the practitioner and nurse practitioner categories, increased in the post-HB1 period. The fact that the number of Kentucky prescribers increases post-HB1 is contrary to what was suggested in the qualitative study presented in Project 2, and provides evidence against a significant chilling effect of HB1.

As described in project 1, HB1 preferentially impacts patient-level prescribing of select drug classes and select drugs within a class. The most significant changes in prescribing at the patient level occurred with the opioids: the mean number of

prescriptions for oxycodone, hydrocodone and oxymorphone - three specific opioids associated with abuse and diversion in Kentucky - decreased in the post-HB1 period while the mean number of prescriptions per patient for other opioids (e.g. morphine, fentanyl and hydromorphone) commonly used to treat chronic cancer pain increased, which provides evidence against a chilling effect of HB1 on opioid prescribing. Similar results are noted for the benzodiazepines more commonly associated with abuse and diversion (alprazolam and diazepam) relative to clonazepam, which is often used for seizure control.

The results of Project 3 highlight the high volume of CS prescriptions written by the top prescribers, showing that between 80 and 90% of the CS prescriptions dispensed (based on drug class) are issued by the top decile of prescribers. The results of Project 3 also show that HB1 likely had a significant impact on inappropriate prescribing, either through the strengthened pain clinic regulations that resulted in closure of several pain clinics immediately following HB1 implementation or through changes in prescribing behavior of individual prescribers who alter treatment decisions as a result of querying the KASPER system under the HB1 mandate. This impact is evident in the 30% decrease in patients receiving prescriptions for the 'holy trinity' and significant decreases in the number of patients receiving high dose oxycodone. Since passage of HB1 and formation of the KASPER Advisory Council, there have been consistent efforts to identify and investigate top prescribers for possible inappropriate prescribing.

Doctor-shopping behavior significantly decreased as a result of HB1 as evidenced by the over 50% decrease in the number of patients meeting the 4 plus 4 criterion of receiving multiple CS prescriptions from 4 or more prescribers dispensed at 4 or more pharmacies in a 3-month period. Significant decreases in the number of patients seeing a large number of prescribers for oxycodone and hydrocodone specifically were also observed in the post-HB1 period.

Finally, analysis of the Treatment Episode Dataset (TEDs) revealed that substance abuse treatment admissions for prescription opioids decreased across the study period with a concurrent increase in treatment admissions related to heroin. When expressed as a percent of all treatment admissions, treatment admissions in Kentucky for prescription opioids decreased at a higher rate while treatment admissions related to heroin increased at a higher rate compared to surrounding states. Similarly, hospital discharges and deaths due to prescription opioid overdose in Kentucky declined post-HB1 while hospital discharges and deaths due to heroin overdose increased. These results suggest the morbidity and mortality related to opioid abuse is shifting away from prescription opioids to heroin.

Several concerns have been raised relative to possible unintended consequences of HB1. For example, it has been suggested that HB1 exerts a chilling effect on CS prescribers such that patients with legitimate medical needs have difficulty accessing

CS therapy. Although qualitative evidence from Project 2 suggests that individual prescribers have opted out of prescribing CS completely as a result of HB1, multiple analyses in this comprehensive evaluation suggest a blanket chilling effect did not occur as a result of HB1.

A second unintended consequence often attributed to HB1 is the rise in heroin abuse. It has been hypothesized that diminished access to and increased cost of prescription opioids as a result of HB1 on doctor-shoppers for prescription opioids has fueled the increases in heroin abuse. A decrease in prescription opioid supply due to HB1 could have resulted in increased costs, which exerted pressure on quantity of prescription opioids demanded and was a likely influence on the market for substitutes such as heroin; however, it should be noted that many external factors likely contributed to the rise in heroin abuse indices. In this evaluation, we document changes in heroin abuse indices, including substance abuse treatment admissions, heroin-related hospitalizations and overdose deaths, that were trending upwards before implementation of HB1 and appear temporally related to the reformulation of OxyContin[®] that occurred in late 2010. The observations suggest that although interventions which impact prescription opioid supply, such as mandatory use of KASPER, alterations in the heroin market were underway prior to HB1 and this policy change should not be viewed as the sole contributor to the rise in heroin abuse in Kentucky.

H. Conclusions and Recommendations

This evaluation shows that HB1, which mandated registration and use of KASPER, significantly impacted the prescribing of select opioids and benzodiazepines in Kentucky, decreased potentially inappropriate prescribing behavior and decreased patient doctor shopping behavior. Multiple analyses argue against a blanket chilling effect of HB1, although stakeholders suggest that individual prescribers have opted out of prescribing CS in Kentucky as a result of the HB1 mandate. High volume prescribers contribute significantly to the overall prescribing of CS in Kentucky and the CHFS should continue to identify and investigate top prescribers for appropriate prescribing practices. Continued analyses of prescribing behavior, patient behavior and outcomes in the post-HB1 period are warranted to determine if the impacts observed in the first year following implementation of HB1 are sustained.